EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE ACT 2004 (SUPPLY OF INFORMATION ABOUT TRANSPLANTS) REGULATIONS 2024

2024 No. 262

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 The Rt Hon Andrea Leadsom MP, Parliamentary Under Secretary of State for Public Health, Start for Life and Primary Care at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 William Vineall, Director of NHS Quality, Safety, Investigations at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Jacky Cooper at the Department of Health and Social Care, email: health.ethics@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument creates a statutory requirement for relevant clinicians to report specified information to the Human Tissue Authority if they are made aware that a patient has received an organ transplant outside the UK or they have a reasonable suspicion that specified offences under human tissue and modern slavery legislation may have been committed.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales, and Northern Ireland.

4.3 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales, and Northern Ireland.

5. Policy Context

What is being done and why?

5.1 The Human Tissue Act 2004 is a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue

from the deceased, for specified health related purposes and public display. The Act also creates offences in relation to the commercial dealings in organs for human transplantation.

5.2 The introduction of Section 32A to the Human Tissue Act 2004 and Section 20A to the Human Tissue (Scotland) Act 2006 by the Health and Care Act 2022 expanded the prohibition on commercial dealings in organs for human transplantation to acts done outside the UK.

5.3 Since the introduction of these sections there has been an increase in suspicious activity being flagged to the police and the Human Tissue Authority, the regulator responsible for living organ donation approvals. This policy seeks to address uncertainty in what information can be reported, and when, by creating a duty to report those suspicions to the Human Tissue Authority.

5.4 The creation of a new statutory requirement to report specified information to the Human Tissue Authority applies to relevant clinicians, who are defined as the doctors and nurses involved in the care and treatment of patients who need an organ transplant, who are receiving an organ transplant, or who have already received an organ transplant.

5.5 The duty will apply to these doctors and nurses practising in transplant and non-transplant centres to ensure the duty applies to clinicians who may come across these patients.

What was the previous policy, how is this different?

5.6 Whilst the offences in human tissue and modern slavery legislation already existed, there was uncertainty among clinicians as to when they could or should share patient information in relation to suspected offences, what information they may share, and with whom they may share it. The statutory duty provides clinicians with the confidence that they are able to, and must, share patient information without contravening other legal or professional duties of confidence. In turn, this increases the UK Government's capacity to detect and prevent offences primarily relating to payment for organs and trafficking potential organ donors.

5.7 There has not been any route by which consistent information is collected on UK nationals who decide to travel overseas for an organ transplant. The introduction of this duty to report information about overseas transplants will provide a data set which will enable the UK Government to understand patterns and scale of overseas organ transplants.

6. Legislative and Legal Context

How has the law changed?

6.1 Section 32 of the Human Tissue Act 2004 creates offences prohibiting commercial dealings in human material for transplantation. Section 32A of the Human Tissue Act 2004 extends the application of the offences in section 32(1) of that Act to actions which take place outside the United Kingdom in certain circumstances. These circumstances are where the person who does the action is habitually resident in England and Wales or is a UK national not habitually resident in Northern Ireland, and the action relates to a human organ. Section 33 creates offences in relation to the use of transplantable material from living donors.

6.2 Section 2 of the Modern Slavery Act 2015 creates an offence where a person arranges or facilitates the travel of another person, with a view to this other person being

exploited. Section 3(4) provides that exploitation includes circumstances where a person is encouraged, required or expected to do anything which involves the commission of an offence under section 32 or 33 of the Human Tissue Act 2004, or which would involve the commission of these offences if it were done in England and Wales. This offence and definition are mirrored in relation to Northern Ireland, in sections 2 and 3(4) of the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) Act (Northern Ireland) 2015.

6.3 Section 34(1) of the Human Tissue Act 2004 provides a regulation making power for the Secretary of State to require specified persons to supply certain information with respect to transplants to a specified authority. This instrument is made under this regulation making power.

6.4 This instrument introduces new statutory duties for certain clinicians to report specified information to the Human Tissue Authority: 1) where a clinician has reasonable suspicion that one or more of the offences listed at 6.1 or 6.2 may have been committed, and 2) where a clinician becomes aware of an organ transplant that has taken place outside the United Kingdom, and the recipient is habitually resident in England, Wales or Northern Ireland, or is otherwise a United Kingdom national.

6.5 These duties only apply where the clinician's reasonable suspicion or knowledge arose in the course of their profession. These duties do not apply where a clinician has reason to believe that another clinician has previously supplied the required information to the Human Tissue Authority, in relation to the same suspected offence or organ transplant.

6.6 Failure to comply with the duties created by this instrument, without reasonable excuse, is an offence under section 34(3)(a) of the Human Tissue Act 2004. A person guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 3 on the standard scale.

6.7 Knowingly or recklessly supplying information which is false or misleading in a material respect, in purported compliance with this instrument, is an offence under section 34(3)(b) of the Human Tissue Act 2004. A person guilty of an offence under this section is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Why was this approach taken to change the law?

6.8 Whilst it was always open to clinicians to report suspected offences under the Human Tissue Act 2004 or Modern Slavery Act 2015, it has become clear that clinicians have concerns about how reporting suspicions might interact with the duties of confidence they owe patients. To address this concern, a statutory duty was considered the most effective way to help detect offences and protect vulnerable patients.

6.9 Creating a statutory duty to report organ transplants which have taken place outside the United Kingdom was considered the most effective way to capture data on where UK nationals and residents are receiving transplants.

7. Consultation

Summary of consultation outcome and methodology

7.1 Section 52(8) of the Human Tissue Act 2004 sets out that before making Regulations under Section 34 of the Human Tissue Act 2004 the Secretary of State must consult with Welsh Ministers and the relevant Northern Ireland department. They are content with the instrument.

7.2 Beyond the consultation required by statute, the Department also worked closely with stakeholders, including NHS Blood and Transplant, the Human Tissue Authority and the National Crime Agency during policy development and whilst drafting these Regulations. The responses were positive with stakeholders agreeing the need for the duty and the approach.

8. Applicable Guidance

8.1 The Human Tissue Authority[1] and NHS Blood and Transplant[2] will publish guidance for relevant clinicians on their respective websites.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because we rely on the Impact Assessment produced for the Health and Care Act 2022. A full Impact Assessment has been produced in relation to the provisions of the 2022 Act[3].

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on business, charities or voluntary bodies because not apply to activities undertaken by business, charities or voluntary bodies.

9.3 The legislation does not impact small or micro businesses.

9.4 There is no, or no significant, impact on the public sector because the instrument simply clarifies the reporting requirement for existing offences.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is through a general approach to sectoral engagement.

10.2 The instrument does not include a statutory review clause as there is no regulatory effect on business.

[1] Home | Human Tissue Authority (hta.gov.uk) https://www.hta.gov.uk/

[2] Home - NHS Blood and Transplant (nhsbt.nhs.uk) https://www.nhsbt.nhs.uk/

[3] Health and Care Act 2022: combined impact assessments - GOV.UK (www.gov.uk) https://www.gov.uk/government/publications/health-and-care-act-2022-combined-impact-assessments

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument introduces new statutory duties using the regulation making power in section 34(1) of the Human Tissue Act 2004. Section 34(3) of that Act creates two offences which apply to regulations made under this power and will therefore be relevant to the enforcement of this instrument.

11.2 Section 34(3)(a) creates an offence for failure to comply, without reasonable excuse, with regulations made under this power. This offence carries a fine not exceeding level 3 on the standard scale.

11.3 Section 34(3)(b) creates an offence for knowingly or recklessly supplying information which is false or misleading in a material respect, in purported compliance with regulations made under this power. This offence carries a fine not exceeding level 5 on the standard scale.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 (“relevant European Union Acts”).