
STATUTORY INSTRUMENTS

2012 No. 1501

**The Quality and Safety of Organs Intended
for Transplantation Regulations 2012**

PART 6

Amendments to other legislation

Amendment of the 2004 Act

25.—(1) The 2004 Act is amended as follows.

(2) In section 14(1) (remit)—

(a) in subsection (1) after paragraph (h) insert—

“(i) the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of human organs, in so far as those activities are activities to which regulation 5(1) of the 2012 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (h).”; and

(b) after subsection (2A) insert—

“(2B) Expressions used in paragraph (i) of subsection (1) and in the 2012 Regulations have the same meaning in that paragraph as in those Regulations.”.

(3) In section 32 (prohibition of commercial dealings in human material for transplantation), after subsection (3) insert—

“(3A) The Authority may not designate a person under subsection (3) to engage in any activity relating to an organ (within the meaning given by Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation) for use for the purpose of transplantation.”.

(4) In section 41(1)(2) (interpretation of Part 2), after the definition of “the 2007 Regulations” insert—

““the 2012 Regulations” means the Quality and Safety of Organs Intended for Transplantation Regulations 2012;”.

(5) In section 59(4) (provisions extending to Scotland)—

(a) before paragraph (a) insert—

“(za) section 13;”, and

(b) in paragraph (f), after “and 61,” insert—

“(fa) Schedule 2;”.

(1) Amended by the Human Fertilisation and Embryology Act 2008 (c.22), Schedule 7, paragraph 23 and by S.I. 2007/1523.

(2) Amended by S.I. 2007/1523.

(6) In Schedule 2(3) (the Human Tissue Authority), at the end of paragraph 1 (membership), insert—

“(3) The Scottish Ministers may nominate a person who is a member of the Authority to make representations about the carrying out of its functions in Scotland.”

(7) In Schedule 3(4) (licences for the purposes of section 16), in paragraph 13 (applications under this Schedule), in sub-paragraph (1), for “and Schedule 1 to the 2007 Regulations” substitute “, Schedule 1 to the 2007 Regulations and Schedule 1 to the 2012 Regulations”.

Amendment of the 2006 Regulations

26. In the 2006 Regulations—

(a) in regulation 2 (interpretation), in the definition of “organ”—

(i) omit “and vital”,

(ii) for “an important” substitute “a significant”, and

(iii) at the end of the definition insert “, and part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation”;

(b) in regulation 11 (cases in which restriction on transplants involving a live donor is disappplied), at the end of paragraph (2) insert—

“and where that referral concerns an organ, the referral must state that the registered medical practitioner, or a person acting under the supervision of that registered medical practitioner—

(a) is satisfied that the donor’s health and medical history are suitable for the purposes of donation; and

(b) has—

(i) provided the donor with the information the donor requires to understand the consequences of donation, and

(ii) endeavoured to obtain information from the donor that is relevant to transplantation.”

(c) after regulation 11(2) insert—

“(2A) In paragraph (2)(b), in cases where the person giving consent is different from the donor, the references to donor shall be read as if they were a references to the person giving consent.”

Amendment of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2004

27. In the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006(5), in regulation 3 (exceptions from licensing requirement)—

(a) in paragraph (3)(a) for “quality assurance”) insert “quality assurance, maintaining the requirements of structure and vascularisation”); and

(b) in paragraph (5)(a) omit “and vital” and for “an important” substitute “a significant”.

(3) Amended by the Health Act 2009 (c.21), Schedule 3, Part 1, paragraph 7.

(4) Amended by S.I. 2007/1523.

(5) S.I. 2006/1260, to which there are no relevant amending instruments.

Amendment of the 2007 Regulations

28. In the 2007 Regulations, in regulation 9(1) (extension of other provisions of the 2004 Act to Scotland), before “15(a)” insert “14 (remit), section”.

Amendment of the 2006 Scotland Regulations

29.—(1) The 2006 Scotland Regulations are amended as follows.

(2) In regulation 2 (cases in which restriction on transplants of organs are disapplied), at the end of paragraph (3) insert—

“, and that referral must state that the medical practitioner is satisfied that the donor’s health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner’s team, has—

- (a) provided the donor with the information required to understand the consequences of donation; and
- (b) endeavoured to obtain information from the donor that is relevant to transplantation.”.

(3) In regulation 3 (cases in which restriction on transplants of organs are disapplied), in paragraph (5), at the end of sub-paragraph (a) omit “and” and after that sub-paragraph insert—

- “(ab) stated in that referral that the medical practitioner is satisfied that the donor’s health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner’s team, has—
 - (i) provided the donor, or one or more of the individuals referred to in paragraph (6) (b), with the information required to understand the consequences of donation, and
 - (ii) endeavoured to obtain from the donor, or one or more of the individuals referred to in paragraph (6)(b), information that is relevant to transplantation; and ”.

(4) In regulation 5 (cases in which restriction on transplants of organs or tissue are disapplied), in paragraph 7, at the end of sub-paragraph (a) omit “and” and insert after that sub-paragraph—

- “(ab) stated in that referral that the medical practitioner is satisfied that the donor’s health and medical history are suitable for the purposes of donation, and that the medical practitioner, or a member of that practitioner’s team, has—
 - (i) provided the donor, or the person referred to in paragraph (8)(b), with the information required to understand the consequences of donation, and
 - (ii) endeavoured to obtain from the donor or the person mentioned in paragraph (8)(b) information that is relevant to transplantation; and”.