
STATUTORY INSTRUMENTS

2024 No. 625

HUMAN FERTILISATION AND EMBRYOLOGY

The Health and Care Act 2022 (Storage of Gametes and Embryos) (Transitional Provision) Regulations 2024

Made - - - - *8th May 2024*
Coming into force - - *10th May 2024*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 186(9) and (11) of the Health and Care Act 2022⁽¹⁾.

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Health and Care Act 2022 (Storage of Gametes and Embryos) (Transitional Provision) Regulations 2024 and come into force on 10th May 2024.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

(3) Paragraph 8 of Part 2 of Schedule 17 to the 2022 Act (interpretation of transitional provision relating to storage of gametes and embryos) applies for the purposes of the interpretation of these Regulations as it applies for the purposes of the interpretation of that Part.

(4) In these Regulations—

“2022 Act” means the Health and Care Act 2022;

“effective consent” means a consent under Schedule 3 to the 1990 Act (consents to use or storage of gametes or embryos etc)⁽²⁾, as that Schedule had effect immediately before the commencement day, which has not been withdrawn;

“maximum storage period”, in relation to a gamete or an embryo, means the maximum period for which the gamete or embryo may be stored under a storage licence;

“relevant day” means 10th May 2024;

“relevant period”—

(a) in relation to a gamete, means a relevant period for the purposes of the following provisions of the 2009 Regulations, as those provisions had effect immediately before the commencement day and as they may be modified by regulations 4 and 5—

(1) [2022 c. 31](#).

(2) The Human Fertilisation and Embryology Act 1990, c. 37. Schedule 3 was amended by section 13 of, and Schedule 3 to, the Human Fertilisation and Embryology Act 2008 ([c. 22](#)) and, with effect from the commencement day, by section 171 of, and Schedule 17 to, the Health and Care Act 2022 ([c. 31](#)).

- (i) regulation 4(1) (gametes: extension of statutory storage period for premature infertility),
 - (ii) regulation 7(4) (transitional provision for gametes: original storage period), or
 - (iii) regulation 8(4) (transitional provision for gametes: extended storage period);
 - (b) in relation to an embryo, means a relevant period for the purposes of the following provisions of the 2009 Regulations, as those provisions had effect immediately before the commencement day and as they may be modified by regulations 4 and 5—
 - (i) regulation 3(1) (embryos: extension of statutory storage period for premature infertility),
 - (ii) regulation 5(5) (transitional provision for embryos: original storage period), or
 - (iii) regulation 6(4) (transitional provision for embryos: extended storage period);
- “treatment services” has the meaning given in section 2(1) of the 1990 Act (interpretation of other terms).

Transitional provision in relation to storage of gametes of certain deceased persons

- 2.—(1) Paragraph (2) applies in a case where—
- (a) the gametes of a person (“P”) are in storage for the purposes of providing treatment services to a person together with whom P was receiving such services,
 - (b) the storage of the gametes is under a pre-commencement storage licence where the maximum storage period applicable immediately before the commencement day was provided for by—
 - (i) regulation 4 (gametes: extension of statutory storage period for premature infertility), 4A (gametes: extension of statutory storage period for premature infertility (coronavirus)), 7 (transitional provision for gametes: original storage period) or 8 (transitional provision for gametes: extended storage period) of the 2009 Regulations, or
 - (ii) regulation 4 of the 2020 Regulations (extension of statutory storage period for gametes: coronavirus),
 - (c) immediately before the commencement day—
 - (i) there was effective consent to the storage of the gametes, and
 - (ii) the maximum storage period applicable to the gametes had not ended, and
 - (d) P died before the commencement day.
- (2) In a case where this paragraph applies—
- (a) subject to regulations 4 and 5, section 14(3) of the 1990 Act (maximum storage periods) has effect on and after the commencement day as if—
 - (i) the 2009 Regulations and the 2020 Regulations had continued in force, notwithstanding the repeal of the power in section 14(5) of the 1990 Act (power to provide for different statutory storage period in certain circumstances) by the substitution in paragraph 2(3) of Schedule 17 to the 2022 Act, and
 - (ii) the 2009 Regulations or the 2020 Regulations, as the case may be, applied for the purpose of determining the maximum storage period applicable to the gametes, and
 - (b) Schedule 3 to the 1990 Act (consents to use or storage of gametes or embryos etc) has effect on and after the commencement day as if paragraphs 11A and 11B (renewal of consent to storage of gametes) were omitted.

Transitional provision in relation to storage of embryos of certain deceased persons

- 3.—(1) Paragraph (2) applies in a case where—
- (a) an embryo, the creation of which was brought about *in vitro* using the gametes of a person (“P”), is in storage for the purposes of providing treatment services to a person together with whom P was receiving such services,
 - (b) the storage of the embryo is under a pre-commencement storage licence where the maximum storage period applicable immediately before the commencement day was provided for—
 - (i) by regulation 3 (embryos: extension of statutory storage period for premature infertility), 3A (embryos: extension of statutory storage period for premature infertility (coronavirus)), 5 (transitional provision for embryos: original storage period) or 6 (transitional provision for embryos: extended storage period) of the 2009 Regulations,
 - (ii) by regulation 3 of the 2020 Regulations (extension of statutory storage period for embryos: coronavirus), or
 - (iii) where the creation of the embryo was brought about *in vitro* on or after the commencement day, by any of the provisions referred to in regulation 2(1)(b)(i) or (ii),
 - (c) immediately before the commencement day—
 - (i) there was effective consent to the storage of the embryo, and
 - (ii) the maximum storage period applicable to the embryo, or to gametes which were used to bring about the creation of the embryo *in vitro* on or after the commencement day, had not ended, and
 - (d) P died before the commencement day.
- (2) In a case where this paragraph applies—
- (a) subject to regulations 4 and 5, section 14(3) of the 1990 Act (maximum storage periods) has effect on and after the commencement day as if—
 - (i) the 2009 Regulations and the 2020 Regulations had continued in force, notwithstanding the repeal of the power in section 14(5) of the 1990 Act (power to provide for different statutory storage period in certain circumstances) by the substitution in paragraph 2(3) of Schedule 17 to the 2022 Act, and
 - (ii) the 2009 Regulations or the 2020 Regulations, as the case may be, applied for the purpose of determining the maximum storage period applicable to the embryo, and
 - (b) Schedule 3 to the 1990 Act (consents to use or storage of gametes or embryos etc) has effect on and after the commencement day as if paragraphs 11C and 11D (renewal of consent to storage of embryos) were omitted.

Storage period definitions and extension of time for obtaining medical opinion

4.—(1) Where the maximum storage period applicable to a gamete or an embryo is determined by the 2009 Regulations or the 2020 Regulations by virtue of regulation 2(2)(a)(ii) or 3(2)(a)(ii), a reference in those Regulations to the “statutory storage period” is to be treated as a reference to that term within the meaning of the 1990 Act immediately before the commencement day.

(2) Where the maximum storage period applicable to a gamete or an embryo is determined by the 2009 Regulations by virtue of regulation 2(2)(a)(ii) or 3(2)(a)(ii), the definition of “maximum storage period” in regulation 2 of the 2009 Regulations is to be read as if the words “under section 14(4) of the Act” and “under section 14(3) of the Act” were omitted.

- (3) Paragraph (4) applies in a case that relates to the storage of gametes where—
- (a) the maximum storage period applicable to the gametes is determined by the 2009 Regulations by virtue of regulation 2(2)(a)(ii),
 - (b) the relevant period applicable to the gametes ended during the period beginning with the commencement day and ending immediately before the relevant day, and
 - (c) the maximum storage period applicable to the gametes could have been increased if—
 - (i) that period had been determined by the 2009 Regulations with effect from the commencement day, and
 - (ii) on any day within the relevant period applicable to the gametes, a registered medical practitioner had given a written opinion that P, or the person together with whom P was receiving treatment services, was prematurely infertile or was likely to become prematurely infertile.

(4) In a case where this paragraph applies, if the opinion referred to in paragraph (3)(c)(ii) is given before 1st January 2025, it is treated, for the purposes of the application of the 2009 Regulations by regulation 2(2)(a)(ii), as having been given immediately before the end of the relevant period described in paragraph (3)(b).

- (5) Paragraph (6) applies in a case that relates to the storage of gametes where—
- (a) the maximum storage period applicable to the gametes is determined by the 2009 Regulations by virtue of regulation 2(2)(a)(ii),
 - (b) the relevant period applicable to the gametes ends during the period beginning with the relevant day and ending with 31st December 2024, and
 - (c) the maximum storage period applicable to the gametes could be increased if, on any day within the relevant period applicable to the gametes, a registered medical practitioner gives a written opinion that P, or the person together with whom P was receiving treatment services, was prematurely infertile or was likely to become prematurely infertile.

(6) In a case where this paragraph applies, if the opinion referred to in paragraph (5)(c) is given before 1st January 2025, it is treated, for the purposes of the application of the 2009 Regulations by regulation 2(2)(a)(ii), as having been given immediately before the end of the relevant period described in paragraph (5)(b).

- (7) Paragraph (8) applies in a case that relates to the storage of an embryo where—
- (a) the maximum storage period applicable to the embryo is determined by the 2009 Regulations by virtue of regulation 3(2)(a)(ii),
 - (b) the relevant period applicable to the embryo ended during the period beginning with the commencement day and ending immediately before the relevant day, and
 - (c) the maximum storage period applicable to the embryo could have been increased if—
 - (i) that period had been determined by the 2009 Regulations with effect from the commencement day, and
 - (ii) on any day within the relevant period applicable to the embryo, a registered medical practitioner had given a written opinion that P, or the person together with whom P was receiving treatment services, was prematurely infertile or was likely to become prematurely infertile.

(8) In a case where this paragraph applies, if the opinion referred to in paragraph (7)(c)(ii) is given before 1st January 2025, it is treated, for the purposes of the application of the 2009 Regulations by regulation 3(2)(a)(ii), as having been given immediately before the end of the relevant period described in paragraph (7)(b).

- (9) Paragraph (10) applies in a case that relates to the storage of an embryo where—

- (a) the maximum storage period applicable to the embryo is determined by the 2009 Regulations by virtue of regulation 3(2)(a)(ii),
- (b) the relevant period applicable to the embryo ends during the period beginning with the relevant day and ending with 31st December 2024, and
- (c) the maximum storage period applicable to the embryo could be increased if, on any day within the relevant period applicable to the embryo, a registered medical practitioner gives a written opinion that P, or the person together with whom P was receiving treatment services, was prematurely infertile or was likely to become prematurely infertile.

(10) In a case where this paragraph applies, if the opinion referred to in paragraph (9)(c) is given before 1st January 2025, it is treated, for the purposes of the application of the 2009 Regulations by regulation 3(2)(a)(ii), as having been given immediately before the end of the relevant period described in paragraph (9)(b).

Storage where relevant period expired without medical opinion before commencement day

5.—(1) Paragraph (2) applies in a case where—

- (a) the gametes of a person (“P”) are in storage for the purposes of providing treatment services to a person together with whom P was receiving such services,
- (b) the storage of the gametes is under a pre-commencement storage licence where the maximum storage period applicable immediately before the commencement day was provided for by regulation 4 (gametes: extension of statutory storage period for premature infertility), 4A (gametes: extension of statutory storage period for premature infertility (coronavirus)), 7 (transitional provision for gametes: original storage period) or 8 (transitional provision for gametes: extended storage period) of the 2009 Regulations,
- (c) the relevant period applicable to the gametes ended before the commencement day without a registered medical practitioner having given a written opinion before the end of that period that P, or the person together with whom P was receiving treatment services, was prematurely infertile or was likely to become prematurely infertile,
- (d) the maximum storage period applicable to the gametes could have been increased if a registered medical practitioner had given such an opinion before the end of the relevant period applicable to the gametes,
- (e) P died before the commencement day, and
- (f) the opinion referred to in sub-paragraph (c) is given before 1st January 2025.

(2) In a case where this paragraph applies—

- (a) for the purposes of the application of regulation 2(2)—
 - (i) the effective consent to the storage of the gametes referred to in regulation 2(1)(c) (i) is not treated as having expired by virtue of the fact that the opinion referred to in paragraph (1)(c) was not given before the end of the period referred to in paragraph (1)(c), and
 - (ii) the maximum storage period referred to in regulation 2(1)(c)(ii) is treated as not having ended before the commencement day, and
- (b) for the purposes of the application of the 2009 Regulations by virtue of regulation 2(2)(a)(ii), the relevant period applicable to the gametes is treated as having begun on the commencement day.

(3) Paragraph (4) applies in a case where—

- (a) an embryo, the creation of which was brought about *in vitro* using the gametes of a person (“P”), is in storage for the purposes of providing treatment services to a person together with whom P was receiving such services,

- (b) the storage of the embryo is under a pre-commencement storage licence where the maximum storage period applicable immediately before the commencement day was provided for by regulation 3 (embryos: extension of statutory storage period for premature infertility), 3A (embryos: extension of statutory storage period for premature infertility (coronavirus)), 5 (transitional provision for embryos: original storage period) or 6 (transitional provision for embryos: extended storage period) of the 2009 Regulations,
 - (c) the relevant period applicable to the embryo ended before the commencement day without a registered medical practitioner having given a written opinion before the end of that period that P, or the person together with whom P was receiving treatment services, was prematurely infertile or was likely to become prematurely infertile,
 - (d) the maximum storage period applicable to the embryo could have been increased if a registered medical practitioner had given such an opinion before the end of the relevant period applicable to the embryo,
 - (e) P died before the commencement day, and
 - (f) the opinion referred to in sub-paragraph (c) is given before 1st January 2025.
- (4) In a case where this paragraph applies—
- (a) for the purposes of the application of regulation 3(2)—
 - (i) the effective consent to the storage of the embryo referred to in regulation 3(1)(c) (i) is not treated as having expired by virtue of the fact that the opinion referred to in paragraph (3)(c) was not given before the end of the period referred to in paragraph (3)(c), and
 - (ii) the maximum storage period referred to in regulation 3(1)(c)(ii) is treated as not having ended before the commencement day, and
 - (b) for the purposes of the application of the 2009 Regulations by virtue of regulation 3(2) (a)(ii), the relevant period applicable to the embryo is treated as having begun on the commencement day.

Signed on behalf of the Secretary of State for Health and Social Care

8th May 2024

Maria Caulfield
Parliamentary Under Secretary of State
Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make transitional provision under section 186(9) and (11) of the Health and Care Act 2022 (c. 31) (the “2022 Act”) in relation to the storage of gametes and embryos for the treatment of a certain cohort of people who died before 1st July 2022. That is the date on which Part 1 of Schedule 17 to the 2022 Act introduced amendments to the Human Fertilisation and Embryology Act 1990 (c. 37) (the “1990 Act”): (a) to extend to 55 years the maximum storage period for gametes and embryos which is provided for in section 14(3) of the 1990 Act and (b) to enable storage of such material for up to 10 years after the death of the person who provided it, after which their consent is taken as withdrawn. Part 2 of Schedule 17 to the 2022 Act made general and specific transitional provision in connection with the effect of those amendments on material already in storage. These Regulations add to the specific transitional provisions in that Part by addressing the duration of consent for the storage of gametes or embryos which began before 1st July 2022, where a person whose material was placed into storage for the purposes of infertility treatment had died before that date and where the maximum storage period applicable to the material was governed by the Regulations referred to in regulations 2(1)(b) and 3(1)(b) of this instrument. In such cases, the maximum period for which the material may be stored is determined by those Regulations, with effect from 1st July 2022, as if the Regulations had continued in force. The new 10 year limit applicable to storage of gametes and embryos after a person has died is also disapplied (regulations 2 and 3).

The maximum storage period for gametes and embryos which was available under the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (S.I. 2009/1582) (“2009 Regulations”) was ten years from the date of first storage, or if later, ten years from the date of the most recent opinion of a medical practitioner that the person who provided the material, or the person with whom they were to be treated, was, or was likely to become, prematurely infertile (“medical opinion”), up to a maximum of 55 years. The medical opinion had to be given before the expiry of each ten-year period (referred to in the 2009 Regulations as the “relevant period”), including posthumously. Regulation 4, paragraphs (3) to (10), addresses situations where a medical opinion would have fallen due during the period beginning with 1st July 2022 and ending with 31st December 2024. If an opinion was not given, but the maximum storage period could have been increased if it had been, the opinion is treated as having been given at the appropriate time, provided it is given by 31st December 2024.

Regulation 5 addresses the situation where a medical opinion had not been given prior to 1st July 2022, resulting in the maximum storage period for gametes or embryos having ended under the 2009 Regulations. If such an opinion is given by 31st December 2024, the maximum storage period is treated as not having ended before 1st July 2022 for the purposes of the application of regulation 2 or 3 to this material. The “relevant period” for such material starts again on 1st July 2022.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.