EXPLANATORY MEMORANDUM TO

THE HEALTH AND CARE ACT 2022 (STORAGE OF GAMETES AND EMBRYOS) (TRANSITIONAL PROVISION) REGULATIONS 2024

2024 No. 625

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health and Social Care.

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

2. Declaration

2.1 Maria Caulfield at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

2.2 Amanda Davies, Deputy Director for Health Ethics, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Steve Pugh at the Department of Health and Social Care Telephone: 02027 210 4350 or email: Steve.Pugh@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 new transitional provision that relates to the storage of gametes and embryos for the treatment of a specified cohort of people who died before the 1st of July 2022 and who had consented to the posthumous use and storage of that material by a named partner. The transitional provision additionally allows the surviving partners of those within that cohort who would have required a medical opinion for extended storage to be allowed additional time to seek a renewed medical opinion if they should wish to.

Where does the legislation extend to, and apply?

4.2 The extent of this instrument is England and Wales, Scotland and Northern Ireland.

4.3 The territorial application of this instrument is England and Wales, Scotland and Northern Ireland.

5. Policy Context

What is being done and why?

5.1 The Human Fertilisation and Embryology Act 1990 ("the 1990 Act") provides the legislative framework for storing gametes and embryos. The maximum storage period,

prior to July 2022, was10 years for gametes and embryos, but it was possible for people who had been certified as prematurely infertile, or who were likely to become prematurely infertile, to store gametes or embryos for an extended period up to 55 years, subject to a requirement to obtain a written medical opinion every 10 years. This ability to extend storage up to 55 years was set out in the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ("the 2009 Regulations").

5.2 Following a public consultation in 2020, the Government decided to modernise the rules to allow for storage limits up to 55 years for all, irrespective of their fertility status, with consent to be renewed every 10 years, in order to offer more choice and simplify the scheme. Changes were also made on rules for posthumous storage of material, where an individual had consented to that use with a named partner, to allow a simpler 10-year storage period that runs from the date of death. The Health and Care Act 2022 ("the 2022 Act") made amendments to the 1990 Act, and set out transitional provisions in connection with this policy.

5.3 During implementation of the changes, the Human Fertilisation & Embryology Authority (HFEA) identified that there was a group of people storing material, who had not been explicitly considered in the design of the changes and therefore whose circumstances had not been expressly provided for in the transitional arrangements where the deceased had consented to a period of storage longer than 10 years and to the posthumous use of their material by a named partner. The effect of the application of the new statutory storage scheme on this identified group is that their surviving partners would lose entitlement to extended storage, and would be limited to 10 years from the date of death.

5.4 In view of this, the Department elected to bring forward an instrument that would restore the position for the affected group and effectively disapply the new provisions relating to posthumous use of material so that the old storage regime continued to apply. A period of time is allowed to enable a written medical opinion, which would have fallen due in the period beginning with the date on which the new regime came into effect, to be obtained.

5.5 The instrument also provides for the situation where material was in storage, with maximum storage periods determined by the 2009 Regulations, and where the necessary written medical opinion had lapsed prior to the commencement of the 2022 Act. The general transitional provisions in the 2022 Act operate to allow storage in these cases to continue until the end of the transitional period (30 June 2024), but do not provide the ability for the affected cohort to obtain renewal of their written medical opinion to allow for storage beyond the end of that transitional period. The instrument therefore also provides that where there were gametes or embryos in storage immediately before commencement of the 2022 Act, and the necessary written medical opinion for ongoing storage had lapsed before that date, affected cohort have until 31 December 2024 to obtain a new written medical opinion to enable continued storage should they wish.

What was the previous policy, how is this different?

5.6 For the cohort of people this instrument applies to, under the scheme created by the 2022 Act, the retrospective application means there could have been significantly reduced periods of allowable storage for posthumous use by a surviving partner. In cases where an individual with material in storage died more than 10 years before the commencement of the 2022 Act, the surviving partner would have no time in which to use that material in treatment once the 2022 Act commenced. This instrument

disapplies certain parts of the new scheme under the 2022 Act and creates new transitional provision preserve the entitlement to storage for the affected cohort as was provided for in the 2009 Regulations. This will allow those individuals to continue to store material for the length of time the deceased had consented to prior to their death.

6. Legislative and Legal Context

How has the law changed?

6.1 The 1990 Act provides the legislative framework for regulating aspects of assisted reproduction, including the creation and use of embryos outside the body, the use of donated gametes in treatment and the storage of embryos and gametes. The 1990 Act, as amended by the Human Fertilisation and Embryology Act 2008 and the 2022 Act, sets the maximum storage limit for gametes and embryos.

6.2 Through amendments made to the 1990 Act by the 2022 Act, the maximum storage limit for gametes and embryos was increased from 10 years to 55 years, with 10-year renewal periods, for all patients who had placed their material in storage, regardless of their fertility status or medical need.

6.3 The amendments made by the 2022 Act also addressed the posthumous storage of gametes and embryos, automatically providing for a further 10 years of storage from the date of death where consent for posthumous use had been given. This was intended to allow the surviving partner sufficient time to grieve, undertake counselling and make decisions about whether to undergo fertility treatment using the gametes or embryos in storage.

6.4 The 2022 Act provided that the new storage provisions applied to material that was placed in storage following commencement of that Act, as well as applying to all material already in storage under a licence issued prior to commencement.

6.5 The 2022 Act also set out transitional arrangements, including a two-year transitional period that runs from 1 July 2022 to 30 June 2024. Within that transitional period, the fertility sector, the regulator and patients are able to make arrangements to comply with the new requirements and resolve any cases where the lawfulness of ongoing storage was in question.

6.6 The transitional arrangements in the 2022 Act did not make express provision for people whose maximum storage periods for gametes and embryos were previously determined by the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 ("the 2009 Regulations") or the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 ("the 2020 Regulations"), and who had died before 1 July 2022. For those people the application of the new provisions inserted into the 1990 Act created a shorter period of storage than they had been entitled to under the 2009 Regulations or the 2020 Regulations.

6.7 This instrument makes transitional provision to amend the maximum storage periods for gametes and embryos in respect of the affected cohort. This is to ensure that no-one with extended posthumous storage entitlement under the previous statutory scheme who died before 1 July 2022 is disadvantaged by the amendments to the 1990 Act, relating to maximum storage periods for gametes and embryos, and the transitional provisions set out in the 2022 Act.

6.8 To address this, new additional transitional provisions apply to this cohort of people providing that the 2009 Regulations and the 2020 Regulations continue in force for

the purpose of determining the maximum storage period applicable to the gametes or embryo.

6.9 This instrument also provides that anyone whose maximum storage is to be determined by the 2009 Regulations or the 2020 Regulations, by virtue of regulation 2 or 3 of the instrument, and who would need to obtain a written medical opinion during the transitional period or during the rest of 2024, but had not done so as a result of the changes to the regime made by the 2022 Act, has until 1 January 2025 to seek that renewed opinion.

6.10 The instrument also provides the same further transitional period, until 1 January 2025, for anyone in the cohort of people to whom the instrument applies, and whose written medical opinion had not been renewed prior to the commencement of the 2022 Act, so in effect whose lawful storage had lapsed. This mirrors the general approach in the transitional provisions in the 2022 Act that affords patients, the regulator and the sector an opportunity to regularise any storage where there is no effective consent.

6.11 The 2020 Regulations provided for an extended period of 12 years of storage for all patients, to reflect the difficulty in obtaining fertility treatment during the pandemic. If the new rules allowing posthumous storage and use for 10 years after a person's death applied to individuals who had died before those rules came into force, the expected period of storage after their death could be reduced. The instrument therefore preserves the application of the maximum storage period under the 2020 Regulations to individuals who died before 1st July 2022, where the storage of their material was governed by those Regulations.

6.12 These transitional provisions do not apply to anyone who had material in storage under the previous statutory scheme but who died after 1 July 2022, which was when the amendments to the rules on maximum storage periods made by the 2022 Act came into force. For those people the new period of 10 years storage from the date of death is less than they would have been entitled to under the old regime, but the changes to the statutory regime happened whilst they were alive. However for those who had material in storage and who died before 1 July 2022, the instrument seeks to remedy the disadvantage caused by the fact that they could not have had knowledge of the changes to the storage rules before they died.

Why was this approach taken to change the law?

6.13 This is the only appropriate approach to make the necessary changes, as at the end of the transitional period material stored by the affected cohort would need to be removed from storage and disposed of.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Government ran a 12-week consultation from February 2020 asking the public for their views about possible changes to the statutory storage limits for eggs, sperm and embryos. 1222 responses were received from a range of stakeholders, including Parliamentarians, individuals and interested organisations with 74% wishing to see the limit increase from the previous 10 years. In response to the consultation, the Government announced that it is changing the storage limit for gametes and embryos to 10-year renewable storage period up to a maximum of 55 years, regardless of medical need.

7.2 A further technical consultation was held on storage issues that were not covered in detail in the original public consultation. This included changes to rules on posthumous use of stored gametes and embryos. Views were sought from several charities, patient groups, expert clinical organisations and public bodies.

7.3 No further consultation on the affected groups has taken place as the instrument seeks to restore entitlement to extended posthumous storage of those who had consented, and died, prior to the coming into force of the 2022 Act. The devolved administrations and the HFEA were consulted and were in support of the approach.

8. Applicable Guidance

8.1 Clinics will receive guidance from the HFEA about the impact and implications of the instrument and any immediate action that needs to be taken. The HFEA will also update its Code of Practice in due course.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument as the costs fall outside the scope of a full Impact Assessment.

9.2 A de minimis assessment has been completed. Based on information provided by the HFEA, the estimated cost to the fertility sector of these changes falls within a potential cost range of £648,000 to £1,296,200.

Impact on businesses, charities and voluntary bodies

9.3 The impact on business, charities or voluntary bodies is minimal.

9.4 The legislation does impact small or micro businesses.

9.5 No specific action is proposed to minimise regulatory burdens on small businesses. It is expected that IVF clinics will recoup this additional cost through their client charges.

9.6 There is no significant impact on the public sector.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring of this legislation will be through regular engagement with the HFEA who will oversee the implementation and report back to the Department on its impact.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 The transitional provisions in this instrument have retrospective effect, insofar as they have effect from the commencement date of the relevant provisions of the 2022 Act, being 1 July 2022, without express authority in the enabling power. However, the retrospection in this instrument is considered necessary to avoid an unforeseen and potentially unfair impact of the general transitional provision in Part 2 of Schedule 17 to the 2022 Act on certain cohorts.

11.2 The retrospection will confer a benefit on the people within that cohort without disadvantaging any other person or the public generally. The general presumption that a power to make subordinate legislation does not enable the making of retrospective provision unless it does so expressly is therefore considered to be rebuttable in this case. The 2022 Act, under which this instrument is made, contains retrospective provision in respect of pre-commencement storage licences relating to gametes and embryos and it follows that where some details of that scheme are set out in subordinate legislation, as in the case of the transitional provision made by the instrument, the power to make that subordinate legislation may similarly be treated as enabling retrospective effect.

11.3 The impact of the amendments to the statutory framework is significant, as the impacted individuals have already died and in some cases their surviving partners, who may have expected to have a number of years to seek treatment using that material in storage would, but for the instrument, already be out of time to do so, it being longer than 10 years since the death of their partner. This impact can only be removed retrospectively and the power to do so is therefore considered to be clearly implicit in the enabling power.

12. European Convention on Human Rights

12.1 As the instrument is not subject to Parliamentary procedure, 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").