

Support for families: NSW exemption to ART donor limit

NSW legislation limits the number of families that can be created with donated embryos or gametes (i.e., ova and sperm) using assisted reproductive technology (ART). Under the *Assisted Reproductive Technology Act 2007* (ART Act), an ART provider must not provide ART treatment using a donated gamete if it is likely to result in offspring being born to more than five women. This is an important protective provision that seeks to limit the number of biological siblings a donor-conceived person has, to reduce the risk of consanguinity.

NSW Health has recently become aware that an ART provider in NSW has been incorrectly interpreting this limit as only applying within NSW, rather than a limit that applied worldwide. As a result, some women were informed by the ART provider that their treatment would be temporarily paused.

The NSW Government recognises the significant emotional, physical and financial impacts a decision to pause ART treatment can have on those women and families, through no fault of their own.

In response, the NSW Government will be creating an exemption to enable any affected women and families to continue their ART treatment.

How will the exemption work?

The NSW Government will create an exemption to enable women and families who are directly affected by an ART provider's incorrect interpretation of the 'five women limit' to continue their treatment.

The exemption will apply to women who, before 1 October 2025, either:

- had an embryo (of the woman or the woman's spouse) held in storage by a registered ART provider, or
- reserved a gamete that was held in storage before 1 October 2025 by a registered ART provider, or
- reserved the use of a particular donor's gamete held outside of NSW, and had commenced preliminary treatment with a registered ART provider after 1 July 2025 for the purposes of receiving ART treatment using that donor's gamete.

The exemption will apply in relation to both:

- gametes or embryos in storage, and
- specific gametes outside of NSW that have been reserved for use by particular women.

The exemption will **not** apply to women and families seeking treatment in the future using gametes or embryos not currently in storage or reserved for use by particular women. The

usual five women limit in the ART Act will apply to all future treatment.

Women (or their spouse) who have already had a child using donated gametes, or using an embryo created from a donated gamete, can continue with any current or future treatment to extend their family using that donor's gametes. The limit in the ART Act does not apply to women in these circumstances.

How and when will the exemption come into effect?

The NSW Government will create the exemption by making amendments to the *Assisted Reproductive Regulation 2024* (Regulation). The amended Regulation will create a class of women who are exempt from the application of section 27 of the ART Act.

The amended Regulation is expected to commence mid-late October 2025.

The NSW Government has decided to provide advance notice of the amending Regulation given the nature of the treatment, recognising the significant emotional, physical and financial impacts a pause to ART treatment can have on affected women and families.

The amended Regulation will likely also include new record keeping obligations for ART providers who provide ART treatment using donated gametes to ensure compliance with section 27 of the ART Act.

What does the exemption mean for ART providers?

To ensure affected women can continue their treatment, the NSW Government will not take regulatory action against an ART provider for a breach of section 27 of the ART Act where they provide ART treatment to women falling within one of the exempted classes between 1 October 2025 and the commencement of the amended Regulation.

Once the Regulation commences, section 27 will not prevent an ART provider from providing ART treatment using a donated gamete to a woman falling within one of the exempted classes, even if offspring of the donor have been born to more than five women.

However, before providing treatment, the ART provider must inform the woman undergoing treatment that offspring of the donor may have been born to more than five women.

What does the five women limit mean for ART providers?

Section 27 of the ART Act continues to apply to ART providers providing treatment to any woman who does not meet the exemption criteria outlined above.

ART providers in NSW must not provide treatment to a woman if the treatment is likely to result in offspring of the donor being born to more than five women whether in NSW or elsewhere, including overseas.

The five women limit includes any woman who has conceived using the donor's gametes, whether through ART treatment or other means, as well as the donor's current partner and any former partners. The limit may be less than five women if a lesser limit is specified by the donor.

This limit has not changed in scope or quantity since the ART Act commenced in 2010.

What penalties do ART providers face for breaches of the five women limit?

NSW Health reminds all ART providers that the NSW Government takes breaches of the ART Act very seriously. The maximum penalty for a breach of section 27 of the ART Act is 800 penalty units in the case of a corporation, and 400 penalty units in any other case (currently \$88,000 and \$44,000 respectively, per breach).