



NATIONAL CENTER FOR LESBIAN RIGHTS



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AB 2356: Equal Access to Fertility Medical Care FAQs for Providers

This bill allows providers to offer people seeking to conceive using a known sperm donor access to certain fertility services on the same terms as different-sex couples. It was authored by Assemblymember Nancy Skinner and co-sponsored by Equality California and the National Center for Lesbian Rights.

Why was AB 2356 needed?

Increasingly, women in same-sex couples, transgender people, and single women are asking trusted friends to act as sperm donors in order to conceive a child. California was the first state to legally recognize that people may use known donors (not just anonymous sperm donors) to conceive a child.

However, people using known donors cannot access the same fertility services as women in different-sex relationships. Different-sex couples can have insemination services using fresh sperm. Known donors' sperm must typically be frozen and quarantined for six months. Insemination using fresh sperm is more effective and less costly.

What does AB 2356 do?

This bill allows providers to provide insemination services using fresh (unfrozen) sperm to people using known donors if the donor and recipient have previously attempted to conceive in a "nonmedical setting" (at home insemination).

Most providers currently are not providing services using fresh sperm except to different-sex couples because federal Food and Drug Administration (FDA) donor testing regulations require retesting within 7 days of each tissue transfer, unless the donor is a "sexually intimate partner." 21 C.F.R. § 1271.90. This retesting process generally requires sperm to be frozen. AB 2356 recognizes that when a recipient has already been exposed to a known donor's semen at home, she can decide to waive these retesting requirements in the same way that a woman may do when she is trying to conceive with her husband or boyfriend.

This bill will not change the requirement that all donors must be tested and that recipients must receive counseling on the risk of sexually transmitted diseases. AB 2356 also requires that any person receiving insemination services without repeat testing must waive repeat testing in writing after being informed of the testing requirements under California law.

Finally, AB 2356 also provides that physicians and surgeons are immune from liability for damages, disciplinary action, or peer review solely based on providing insemination services without repeat testing so long as 1) the recipient gives informed consent, and 2) the initial

testing and counseling requirements in California Health & Safety Code Section 1644.5 are met. The law also exempts tissue banks from disciplinary action against their licenses if these requirements are met.

What is required for a written waiver of repeat testing?

AB 2356 requires that a recipient “may waive a second or other repeat testing of that donor if the recipient is informed of the requirements for testing donors under [Cal. Health & Safety Code § 1644.5] and signs a written waiver.”

In order to provide services without retesting at each insemination attempt, providers must provide recipients with information about the testing requirements in California Health & Safety Code Section 1644.5, and the recipient must sign a written waiver stating that she has been informed of these requirements and chooses to waive second or repeat testing. Providers should also ensure that practices are in place to verbally explain the testing requirements in a clear, understandable manner.

We strongly recommend that providers obtain advice from legal counsel about the necessary requirements for written waivers and have their waivers reviewed by counsel.

Is there any risk to providers’ FDA licensure if they provide these services?

FDA regulations are federal law and apply to any person or agency involved in the transfer of human tissues. AB 2356 is a California law that provides guidance for how to interpret a term in FDA regulations that is not defined. The FDA has the ultimate authority to define terms in its regulations. AB 2356 provides that it clarifies that the term “sexually intimate partner” under FDA regulations applies to a known donor if the recipient has already been exposed to his semen in a nonmedical setting until the FDA explicitly defines this term.

California has a history of providing guidance about sperm donation and assisted reproduction in areas not specifically addressed by the FDA. California was the first state to address known or “designated donors,” a term later adopted by the FDA. California also began allowing insemination services to be provided to HIV-negative women using sperm from an HIV-positive partner, so long as certain procedures are followed to reduce risk of transmission, before the FDA addressed this issue.

Any person or entity involved in the transfer of human tissue must follow FDA regulations. The FDA inspection or investigations process has many steps – even if the FDA determines that it does not approve of the definitions provided by AB 2356, it will begin with a warning to stop providing these services. The sponsors of this legislation believe that the risk to individual providers is low, and we are committed to continuing to work with the FDA to explicitly allow provision of insemination services using fresh sperm from known donors.

We strongly recommend that providers obtain advice from legal counsel about their responsibilities under both state and federal law. NCLR has a list of attorneys who have indicated that they have advised clinics in the past about their responsibilities. We are not a formal referral provider, and we cannot vouch for their expertise or whether they will be able to advise you. If you are an attorney working with a provider, NCLR is available to discuss this law and its application. Our contact information is provided below.

Wasn’t it possible to provide insemination services using fresh sperm from known donors before this law?

Yes, AB 2356 provides clarification and guidance about the term “sexually intimate partner” – and some providers already operated under the definition in AB 2356 that any recipient previously exposed in a nonmedical setting could receive these services.

Additionally, FDA regulations already clearly allow providers to provide insemination services using fresh sperm when all FDA retesting requirements are met within 7 days of the insemination – although this is typically quite costly and practically difficult.

When does AB 2356 go into effect?

This law goes into effect January 1, 2013. Each provider will be able to decide when and if to offer these services – the law does not require providers to offer this service.

For more information, contact the National Center for Lesbian Rights Legal Helpline at 800-528-6257 or info@nclrights.org