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California Department of Public Health



EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
EXEMPT-11-004 Tissue Donors: HIV Sperm Washing
Notice Posted: June 19, 2017

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

Commencing (45-days after the notice is published), the Department will conduct a 30-day comment period during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action.

PUBLIC HEARING

If a member of the public requests a public hearing during the 30-day comment period, the hearing shall be held prior to the adoption of the regulations. If no member of the public requests a public hearing, the regulations shall be deemed adopted at the conclusion of the 30-day comment period.

For individuals with disabilities, should a hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading, or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note: The range of assistive services available may be limited if requests are received less than ten business days prior to public hearing.

To request such services or copies of material in an alternate format, please write or call: Julia Robinson, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, at (916) 558-1710, email to julia.robinson@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Any written comments pertaining to this proposal, regardless of the method of transmittal, must be received by Office of Regulations by 5:00 p.m. on September 5, 2017, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.



Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier “EXEMPT-11-011 Tissue Donors: HIV Sperm Washing” in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 440-5747;
3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments should include the regulation package identifier, “EXEMPT-11-011 Tissue Donors: HIV Sperm Washing”, author’s name and mailing address.

BACKGROUND

State law limits the transfer of tissues into the body of another person by means of transplantation, from a donor who has been screened and found reactive for HIV, human T lymphotropic virus-1 (HTLV), viral hepatitis B or C (HBV and HCV), or syphilis. A recipient testing non-reactive may only consent to therapeutic insemination of sperm from a reactive donor if the donor is the spouse of, partner of, or designated donor for that recipient.

Sperm whose donor has tested reactive for HIV or HTLV may be used for the purpose of insemination or ART for a recipient testing non-reactive for HIV or HTLV only after the donor’s sperm has been effectively processed to minimize the infectiousness of the sperm for that specific donation. Sperm processing minimizes the risk of transmission of HIV and HTLV, allowing a reactive donor and a non-reactive recipient to more safely utilize insemination or ART.

Health and Safety Code section 1644.5 directs the Department to adopt regulations prescribing standards for the handling and storage of sperm samples of carriers of HIV and HTLV in facilities that perform sperm processing. This statute exempts adoption of these regulations from the rulemaking requirements of the Administrative Procedure Act (Health & Saf. Code, § 1644.5, subd. (c)(3)(B)(ii).). Any future amendments to these regulations are also APA-exempt. (Id.) Because these regulations are APA-exempt, an initial statement of reasons, informative digest, and fiscal and economic analyses are not required.

To fulfill its statutory mandate, the Department is adopting the recommendations made within the “Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment With the Use of Autologous Gametes: A Committee Opinion,” published by the American Society for Reproductive Medicine (ASRM) in 2012. ASRM is the recognized leader in reproductive medicine, and Health and Safety Code section 1644.5 specifically references the ASRM recommendations as the standards the Department

may propose to adopt. The ASRM recommendations promote safe processing of sperm from seminal fluid to minimize HIV or HTLV infectivity while maintaining viability for insemination. If later publications of the ASRM guidelines alter these recommendations, these shall be reviewed by the Department and accepted or not accepted.

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Holly Pearson, Attorney, Office of Legal Services, at (916) 327-4310.

All other inquiries concerning the action described in this notice may be directed to Julia Robinson, Office of Regulations, at (916) 445-2529.