



# Oversight of IVF in the US

In the United States, medical care is regulated by a complex and comprehensive network of federal and state regulations and professional oversight. In vitro fertilization (IVF), a medical treatment commonly used by those who require medical intervention to build their families, is no exception.

## Federal

### Food and Drug Administration (FDA)

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The FDA approves and regulates drugs and devices in all areas of medicine, including those used during the IVF process.

If a patient uses donor gametes, those tissues are subject to additional FDA screening. The FDA also enforces regulations pertaining to physical facilities and record keeping for practices that utilize donated tissue. FDA staff conducts inspections and has the authority to issue fines and shut down any non-compliant facilities.

### Clinical Laboratory Improvement Acts (CLIA)

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The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.

Diagnostic clinical laboratory tests—which, in the IVF process, mostly involve the measurement of hormone levels—are subject to rigorous oversight under CLIA.

### Centers for Disease Control (CDC)

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In 1992, Congress passed the Fertility Clinic Success Rate and Certification Act<sup>1</sup>, requiring any physician who performs an IVF procedure to report the procedure and its outcome to the CDC. This law establishes a framework to track the outcomes of individual fertility clinics throughout the country. This transparency is a singular requirement to the United States medical field, producing a unique set of outcomes data unavailable for most other clinical procedures.

# States

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The licensing of medical providers is under the purview of the states, whereby each state licenses the professionals who provide care for patients. In the case of IVF procedures, this includes physicians, nurses, embryologists, mental health professionals, and, in some states, genetic counselors.

States are also the locus of family law in the United States. Thus, questions regarding establishing or transferring parentage rights and responsibilities, which may come up with the use of tissue donations or gestational surrogacy, are under the auspices of state law.

## Professional oversight

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Throughout American medicine, professional oversight plays an important role. All medical specialties have independent boards to credential physicians. The American Board of Obstetrics and Gynecology certifies physicians in both general OBGYN and the subspecialty of Reproductive Endocrinology and Infertility.

The Society for Assisted Reproductive Technology (SART) is an affiliate group of the American Society for Reproductive Medicine that accredits and oversees IVF clinics. To be a SART member, clinics must meet a rigorous set of standards, including credentialing of clinic staff, accreditation of their laboratory, and adherence to the routinely updated Practice and Ethics guidelines set by ASRM. SART reports birth outcomes from its member clinics so that patients can make informed decisions. The group sets guidelines for best practices in IVF and plays a major role in quality assurance.

**The bottom line is that IVF is already one of the most heavily regulated procedures in all American medicine.**

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For almost a century, the American Society for Reproductive Medicine (ASRM) has been the global leader in multidisciplinary reproductive medicine research, ethical practice, and education. ASRM impacts reproductive care and science worldwide by creating funding opportunities for advancing reproduction research and discovery, by providing evidence-based education and public health information, and by advocating for reproductive health care professionals and the patients they serve. With members in more than 100 countries, the Society is headquartered in Washington, DC, with additional operations in Birmingham, AL. [www.asrm.org](http://www.asrm.org) | [publicaffairs@asrm.org](mailto:publicaffairs@asrm.org)

<sup>1</sup> H.R.4773 - 102nd Congress (1991-1992): Fertility Clinic Success Rate and Certification Act of 1992 | [Congress.gov](https://www.congress.gov) | [Library of Congress](https://www.libraryofcongress.gov)