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IN FOCUS

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Assisted Reproductive Technology Regulation and Oversight

There has been growing interest from Congress and the Trump Administration in the availability and regulation of infertility services in the United States, which include assisted reproductive technologies (ART). Fertility clinics, embryology and clinical laboratories, and health care providers providing these services in the United States are subject to regulation and oversight at both federal and state levels. This *In Focus* describes ART, the entities involved, and mechanisms of selected federal and state oversight of such entities.

Assisted Reproductive Technology

The term *assisted reproductive technology* (ART) refers to treatments or procedures to help achieve a pregnancy in which human oocytes or embryos are handled outside the body. Individuals or couples may seek ART for a variety of reasons, including to address *infertility*. Infertility is a reproductive health disorder generally defined as the inability to achieve a successful pregnancy after a certain time period of attempting to become pregnant. The most common ART procedure is in vitro fertilization (IVF), but also includes gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT). IVF consists of several steps and can be referred to as an ART *cycle*. The basic procedures of an ART cycle typically include

- *Ovarian Stimulation* – A female patient is prescribed medications which stimulate her ovaries to prepare to produce multiple oocytes (human eggs).
- *Oocyte Retrieval* – The resulting oocytes are removed from the ovaries before ovulation occurs during a surgical procedure at a fertility clinic. These retrieved oocytes might then be frozen for future use.
- *Fertilization of the Oocytes* – The retrieved oocytes are either thawed and combined with sperm or, shortly after retrieval, combined with sperm in an embryology laboratory with the purpose of fertilizing the oocytes to develop into an embryo.
- *Embryo Culture* – The fertilized oocytes are cultured in the laboratory to develop into embryos. Embryos that develop appropriately are then prepared for transfer or frozen for later use.
- *Embryo Transfer* – An embryo, either fresh or frozen, can then be transferred into the uterine cavity. This may result in a pregnancy if the embryo successfully attaches to the uterine lining.

ART cycles can involve other procedures or variations of the procedures briefly summarized above, depending on factors like an infertility diagnosis or whether donated material is being used. Multiple treatment cycles may be needed to achieve a successful pregnancy.

Infertility can be influenced by age, reproductive organ damage, hormone imbalance, genetic disorders, or certain medical treatments. Treatments for infertility thus may involve other non-ART services such as surgery, hormone or other medication therapy, genetic counseling, or medical procedures in which only sperm are handled such as intrauterine insemination (IUI).

Regulation and Oversight of ART Entities

The provision of ART services involves multiple entities, which the federal government regulates in various capacities. These include fertility clinics, embryology and clinical laboratories, and the health care professionals providing ART services. These entities are subject to federal oversight and regulation specific to the ART services they provide.

Fertility Clinics

ART services are provided at specialized clinics, often referred to as *fertility clinics*. According to the most recently published annual report, in 2021 there were roughly 500 fertility clinics operating in the United States. Fertility clinics are required to follow ART-specific federal requirements established under the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA, P.L. 102-493).

The Centers for Disease Control and Prevention (CDC) conducts the data standardization and reporting requirements under FCSRCA for all fertility clinics in the United States. According to FCSRCA (42 U.S.C. §§263a–1-263a–7), fertility clinics that provide any "treatments or procedures which include the handling of human oocytes or embryos," are required to annually report ART cycle characteristics and outcomes and which embryology laboratories the clinic works with to the CDC. The CDC collects this data through the National ART Surveillance System (NASS), a web-based data collection system. The CDC aggregates this data into an annual report: *Assisted Reproductive Technology Fertility Clinic National Summary Report*.

The annual report for 2021 included data from 453 clinics which reported roughly 414,000 ART cycles were performed resulting in 92,000 live births, roughly 2.5% of all births in the United States that year. The number of ART cycles and resulting live births has been steadily increasing over time, with the number of annual ART cycles more than doubling over the last decade according to the 2021 annual report. All U.S. fertility clinics and their associated embryology laboratories are listed in the annual report. In 2021 roughly 50 clinics did not submit data to the CDC or did not approve their data to be included in the report.

The main purpose of the ART report is to inform patients, and the focus is on success rates resulting in live births. Fertility clinics have an incentive to report to show

potential clients their success rates, and clinics that do not report or do not verify their data are included in the report as non-compliant clinics. The CDC has modified the data collected from fertility clinics over time to both better capture available procedures and to track emerging trends, with the most recent change published in August 2024.

The ART industry has self-regulatory organizations that produce guidelines, best practices, and ethical standards in ART for fertility clinics, clinical laboratories, and ART professionals. The American Society for Reproductive Medicine (ASRM) and its affiliate the Society for Assisted Reproductive Technology (SART) are the major organizations establishing professional standards in ART.

Embryology and Clinical Laboratories

Fertility clinics work with clinical and embryology laboratories that specialize in embryology, andrology, and endocrinology to provide the services needed for ART, such as semen analysis, blood tests, oocyte and sperm handling, and embryo culture and development.

Federal law and regulations require clinical laboratories that perform diagnostic tests on humans to abide requirements and guidelines established through the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (P.L. 100-578) and associated regulations (42 C.F.R. Part 493). All clinical laboratories that perform testing on humans in the United States, including the diagnostic tests used in reproductive medicine, are regulated by the Centers for Medicare & Medicaid Services (CMS) through CLIA. The objective of CLIA is to ensure quality laboratory testing by establishing standards for accuracy, reliability, and timeliness of patient test results. Laboratories performing tests used in the diagnosis of infertility, such as semen and blood analysis, are covered by CLIA. Embryology laboratories performing procedures including oocyte fertilization, embryo culture, and cryopreservation of embryos are not subject to requirements under CLIA, as these procedures are not diagnostic tests.

The FCSRCA includes a certification requirement specific to embryology laboratories, codified under 42 U.S.C. §263a-2. Certification of embryology laboratories is currently carried out by two non-governmental laboratory accreditation programs: the Joint Commission Laboratory Accreditation Program and the College of American Pathologists (CAP) Reproductive Laboratory Accreditation Program. The accreditation status of each fertility clinic's embryology laboratory is published in the annual ART report from the CDC. Separately, the CMS has approved the Joint Commission and CAP as organizations that may accredit clinical laboratories for the purposes of complying with CLIA requirements.

The Food and Drug Administration (FDA) regulates human cells, tissues, and cellular or tissue-based products (HCT/Ps) and generally requires donors be screened according to specific guidelines and entities handling HCT/Ps to follow certain requirements. Reproductive tissues including human eggs, sperm and embryos are regulated as HCT/Ps by the FDA. Federal regulations under 21 C.F.R. Part 1271 require ART clinical laboratories, reproductive tissue banks, and other entities handling HCT/Ps to follow registration, donor screening, labeling, and other processes to prevent the spread of communicable diseases. Entities using HCT/Ps are required to register with the FDA and are subject to unannounced, periodic inspections for compliance with federal regulations.

In 2016, the FDA amended existing regulations to increase access to donated embryos for reproductive use. The FDA issued a final rule which provided additional flexibility under 21 C.F.R. § 1271.90(b). The final rule clarified that if an embryo was originally intended for a specific individual or couple, its use for directed or anonymous donation would not be prohibited under HCT/P regulations, even when the applicable donor eligibility requirements are not met. The FDA provides screening and testing recommendations for directed or anonymous embryo donation rather than requirements, but encourages complete testing and screening of the gamete donors. Some states impose additional requirements for reproductive tissue banks.

Health Care Providers

States have the primary role in governing and regulating health provider licensing, continuing medical and legal education, and discipline for medical and legal misconduct regarding ART professionals. For licensure, states require health professionals to graduate from accredited schools deemed acceptable by state boards of medical and allied health examiners and to pass state-mandated examinations.

Some states have enacted laws specific to the misconduct of medical ART professionals. Federal criminal laws have also been used to charge health care providers in cases of providers misrepresenting the source of sperm, oocytes, or embryos to their patients in cases of fertility fraud.

Considerations for Congress

The 119th Congress has expressed an interest in the federal oversight of ART, including data collection and surveillance activities by the CDC. House and Senate Appropriations Committee reports accompanying proposed FY2026 appropriation bills for the Departments of Labor, Health and Human Services, and Education, and Related Agencies (LHHS) both address the CDC's ART surveillance activities. The annual LHHS appropriations bill provides funding for the CDC, which includes its ART surveillance activities as required by FCRSCA. H.Rept. 119-271 accompanying H.R. 5304 affirms the CDC's role in collecting and publishing national ART data and further directs the CDC to begin publishing data: (1) on health complications experienced by egg donors and women undergoing fertility treatments, and (2) related to the number of eggs fertilized and embryos created in each ART cycle, as well as their outcome including their natural demise or disposal. S.Rept. 119-55 accompanying S. 2587 directs the CDC to restore its ART surveillance work back to full capacity, following the termination of the researchers at the CDC in April 2025 who conduct ART surveillance and manage the NASS. Congress could maintain the status quo, or consider amending current statute to reflect data elements of interest and/or processes by which data are collected.

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