# HOUSE . . . . . No. 5050

## The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, June 9, 1994.

The committee on Health Care, to whom was referred the petition (accompanied by bill, House, No. 2062) of John H. Rogers and other members of the House for legislation to further regulate fertility clinics and embryo laboratories, reports recommending that the accompanying bill (House, No. 5050), ought to pass.

For the committee,

CARMEN H. BUELL.

# The Commonwealth of Massachusetts

In the Year One Thousand Nine Hundred and Ninety-Four.

AN ACT RELATIVE TO THE TREATMENT OF INFERTILITY.

*Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:*

SECTION 1. Section 1 of chapter 111D of the General Laws as appearing in the 1992 Official Edition is hereby amended by adding before paragraph (1) the following new paragraph: —

(1) "assisted reproductive technology", any treatment or procedure which includes the manipulation of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, and such other specific technologies, natural and non-natural, as the commissioner may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person.

Said section of said chapter is hereby further amended in line 3 by renumbering the paragraph contained therein (2).

Said section of said chapter is hereby further amended in line 7 by renumbering the paragraph contained therein (3).

Said section of said chapter is hereby further amended in line 8 by renumbering the paragraph contained therein (4).

Said section of said chapter is hereby further amended in line 10 by renumbering the paragraph contained therein (5).

Said section of said chapter is hereby further amended in line 18 by renumbering the paragraph contained therein (6).

Section 1 of chapter 111D of the general laws as appearing in the 1992 Official Edition is hereby further amended by adding after paragraph (5) the following new paragraph: —

(6) "Embryo laboratory", any facility in which human oocytes are subject to assisted reproductive technology treatment or procedure based on manipulation of oocytes or embryos which are subject to implantation.

Said section of said chapter as so appearing is hereby further amended in line 20 by renumbering the paragraph contained therein (7).

Said section of said chapter is hereby further amended by adding after the aforementioned paragraph (7) the following new paragraph: —

(8) "Fertility clinic", any facility, hospital, institution, physician's office or other place which offers and provides to the public assisted reproductive technology services or other such services intended to give medical assistance to persons apparently incapable of achieving pregnancy absent medical assistance.

Said section of said chapter as so appearing is hereby further amended in line 23 by renumbering the paragraph contained therein (9).

Said section of said chapter as so appearing is hereby further amended in line 27 by renumbering the paragraph contained therein (10).

SECTION 2. Chapter 111D is hereby further amended by adding after section 3, the following section: —

Section 3A. The commissioner shall appoint an Assisted Reproductive Technology Advisory Committee, hereafter referred to as the committee, to consult with the department in the administration of this act. The committee shall be composed of five persons representing medical specialists in assisted reproductive technology, patient and consumer advocates, and a member of the Bar with expertise and knowledge in the legal and ethical issues involved with assisted reproductive technologies.

The commissioner shall appoint one member as chairman. Each member shall hold office for a term of four years and without compensation, and until his successor is appointed and qualified.

The committee shall meet as frequently as the chairman deems necessary, but not less than twice a year.

The committee shall monitor and evaluate the implementation of this act, including, among other things; coordination and development of a clinic registry; oversight of fertility clinic reporting to the Department; and implementation of a program to ensure the accreditation of all embryo laboratories utilized by said clinics, such as the College of American Pathologists' Reproductive Laboratory Accreditation Program.

The committee shall further study, evaluate and report on the Fertility Clinic Success Rate and Certification Act, (Public

Law #103-493) which was enacted October twenty-fourth, nineteen hundred and ninety-two, and directs the U.S. Secretary of the Department of Health and Human Services to develop a voluntary model program for the certification of embryo laboratories for distribution to the states by October twenty-fourth, nineteen hundred and ninety-four.

The committee shall report on its progress and findings on an annual basis to the commissioner, the secretary of health and human services, the governor, and the joint committee on health care.

SECTION 3. Chapter 111D as so appearing is hereby amended by adding after section 13 the following section: —

Section 14. (a) Each fertility clinic, as defined in section one, shall annually register with the Department the names of all persons conducting or assisting in assisted reproductive technology procedures and treatment, and the locations where said procedures and treatment are conducted.

(b) Each fertility clinic shall annually report to the Department, pregnancy success rates achieved by such clinics through each assisted reproductive technology, and the identity of each embryo lab as defined in section one, used by such clinic. The Department shall require said reports to be in the same format as those reported to the Society For Assisted Reproductive Technology (SART), and to the U.S. Secretary of Health and Human Services under the Fertility Clinic Success Rate and Certification Act of 1992 (Public Law #103-493).

For the purposes of this section, the definition of "pregnancy success rates" shall take into account the effects on age, diagnosis, and other significant factors, and shall include in such rates:

(1) the basic live birth rate calculated for each assisted reproductive technology performed by a fertility clinic, by dividing the number of pregnancies which result in one or multiple live births by the number of ovarian stimulation procedures attempted by such clinic, and

(2) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by a fertility clinic, by dividing the number of pregnancies which result in one or multiple live births by the number of successful oocyte retrieval procedures performed by such clinic.

SECTION 4. Chapter 111D is hereby further amended by adding after section 14 as so created by this act, the following section: —

Section 15. (a) Fertility clinics shall obtain written informed consent from each patient after providing patients with detailed written information on the following: i) the nature of the proposed treatment; ii) the success rate of performing said proposed treatment; iii) the experimental nature of the treatment or of any individual aspect of the treatment, including the use of fertility drugs; iv) all possible medical risks to the patient and to any possible offspring; v) all possible side effects of the treatment; vi) all appropriate medical and non-medical alternatives; and vii) the availability of independent counselling and support services.

(b) Said clinics shall also obtain written informed consent form all participating oocyte donors before commencing any aspect of the procedure. Before consent is obtained, clinics shall provide said donors with detailed written information regarding the nature and expected duration of said donor's involvement, and all possible short- and long-term risks and side effects of the procedure, including drug therapy.

SECTION 5. Section 24B of chapter 111 as so appearing in the 1992 Official Edition of the General Laws is hereby amended by adding the following paragraph: —

Notwithstanding any general or special law to the contrary, the standard certificates of live birth prescribed by the commissioner shall include in the part of said certificate bearing the caption "Confidential Information" a space for information relative to whether a birth was the result of any assisted reproductive technology, as so defined in Section 1 of this act.

SECTION 6. Chapter 112 of the General Laws as so appearing in the 1992 Official Edition is hereby amended by adding after section 11 the following new section: —

Section 11A. The board shall by regulation establish qualifications, standards and criteria no less stringent than the most current standards of the American College of Obstetrics and Gynecology and the American Fertility Society, and consistent with the

Fertility Clinic Success Rate and Certification Act of 1992 (Public Law #103-493), which shall apply to all physicians who perform assisted reproductive technologies in the treatment of infertility.