HOUSE . . . . . No. 2062

By Mr. Rogers of Norwood, petition of John H. Rogers and other members of the House for legislation to further regulate fertility clinics and embryo laboratories. The Judiciary.

The Commonwealth of Massachusetts

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

AN ACT REGULATING FERTILITY CLINICS AND EMBRYO LABORATORIES.

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. The General Laws, as appearing in the 1992 Official Edition, are hereby amended by inserting after Chapter 111H the following new chapter:—

CHAPTER 111I
Fertility Clinics and Embryo Laboratories

Section 1. As used in this chapter, unless the context clearly indicates otherwise, the following words shall have the following meanings:

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

(2) "commissioner", the commissioner of public health.

(3) "department", the state department of public health.

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

(5) "fertility clinic", any facility, hospital, institution or other place which offers and provides to the public assisted reproductive technology programs or other such programs intended to give medical assistance to persons apparently incapable of achieving pregnancy absent medical assistance.

Section 2. (a) The commissioner is hereby authorized and directed to promulgate rules and regulations for the licensing of fertility clinics. Such rules and regulations shall include the following requirements:

(l) a standard for the type of training and experience which a physician must undergo before a physician may perform assisted reproductive technologies on patients;

(2) a standard for the length of training and experience which a physician must attain before a physician may perform assisted reproductive technologies on patients;

(3) a standard to prohibit, such clinics from causing unreasonable waiting periods for patients once a patient has been approved by such a clinic for assisted reproductive treatment;

(4) a standard for the hours of operation of such clinics to provide necessary access for patients to meet the best medical interests of any patient;

(5) a standard for the full disclosure by such clinics to patients in a writing signed by said patients regarding all assisted reproductive technologies, regardless of whether any such clinic provides any such technology;

(6) a standard for the maintenance of records on biological and medical histories of donors of human oocytes and human sperm and the release of such records to the commissioner upon demand;

(7) a standard for the full disclosure by such clinics to patients regarding information required to be maintained under subsection (6) when in the best medical judgment of the clinic such information is germane to the treatment of a patient;

(8) a standard for the maintenance of records on the professional background of personnel employed by such clinics, including information regarding work experience. training in the fertilization field, and education, and the release of such records to the commissioner upon demand and thereafter to be made available to the public;

(9) a standard for the amount of money, not covered under an indemnification policy, if any, of a patient, which must be paid by the patient before such clinic will commence assisted reproductive treatment of such patient;

(10) a standard that each patient receive a detailed written summary from the treating physician regarding the method of treatment after each assisted reproductive technology so performed on said patient for the use by said patient to compare with other such technologies in planning possible future treatments of said patient;

(11) a standard that each clinic shall annually survey present and former patients of said clinic on the medical status of said patients and their children, if any, born as a result of any assisted reproductive technology or as a result of natural reproduction achieved subsequent to treatment by said clinic.

(b) In developing the rules and regulations under paragraph (a), the commissioner shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with fertility clinics.

Section 3. The commissioner shall administer the licensing of fertility clinics and shall provide forms for the application for a license and forms for the application for the renewal of such a license which shall be submitted by the clinic at the time of changes on the ownership of a licensed clinic or changes in the administration of such a clinic. The term of a license issued by the commissioner shall be prescribed by the commissioner and shall be valid for a period of time to be defined by the commissioner by the public comment process. The commissioner shall require payment of fees for the issuance and renewal of licenses in such an amount sufficient to cover the cost to carry out this chapter based on the volume and scope of the services being performed by the fertility clinics.

Section 4. (a) A license issued by the commissioner under section 3 for a fertility clinic shall be revoked or suspended if the commissioner finds, on the basis of inspections and after reasonable notice and opportunity for hearing to the owner or operator of the clinic, that the owner or operator or any employee of the clinic:

(l) has been guilty or misrepresentation in obtaining the license.

(2) has failed to comply with any standards under section 2 applicable to the license,

(3) has refused a request of the commissioner for permission to inspect the clinic. its operations, or its records.

(b) If the license of a fertility clinic is revoked or suspended, the license of the clinic shall continue in effect for sixty days after the clinic receives notice of such revocation or suspension. If the license of a clinic is revoked or suspended, the clinic may apply to reinstate such license after one year following the date of the revocation or suspension.

Section 5. (a) Each fertility clinic shall periodically report to the commissioner through the department:

(1) pregnancy success rates achieved by such clinic through each assisted reproductive technology, and

(2) the identity of each embryo laboratory used by such clinic and whether such laboratory is certified under section 7 or has applied for such certification.

(b)(1) For the purposes of subsection (a)(1), the commissioner shall, in consultation with the organizations referenced in paragraph (c), define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person during its development.

(2) In developing the definition of pregnancy success rates, the commissioner shall take into account the effects on success rates of age, diagnosis, and other significant factors and shall include in such rates:

(A) 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 live births by the number of ovarian stimulation procedures attempted by such clinic, and

(B) 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 live births by the number of successful oocyte retrieval procedures performed by such clinic.

(c) In developing the definition under paragraph (b), the commissioner shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating

professional services and embryo laboratories associated with fertility clinics.

Section 6. The commissioner is hereby authorized and directed to promulgate rules and regulations for the certification of embryo laboratories to assure that the procedures in such laboratories are effectively performed. Such rules and regulations shall include the following standards:

(1) a standard to assure consistent performance of procedures by each embryo laboratory;

(2) a standard for a quality assurance and a quality control program to assure valid, reliable, and reproducible procedures within the laboratory;

(3) a standard for the maintenance of records on laboratory tests and procedures performed, including the scientific basis of, and the methodology used for, the tests, procedures, and preparation of any standards or controls, criteria for acceptable and unacceptable outcomes, criteria for sample rejection, and procedures for safe sample disposal;

(4) a standard for the maintenance of written records on personnel and facilities necessary for proper and effective operation of the laboratory, schedules of preventative maintenance, function verification for equipment, and the release of such records to the commissioner upon demand; and

(5) a standard for the use of such personnel who meet such qualifications as the commissioner may develop.

Section 7. (a) The commissioner shall administer the certification of embryo laboratories and shall provide for the inspection and certification of such laboratories by the commissioner or by accreditation organizations approved by the commissioner. The commissioner shall provide forms for the application by an embryo laboratory for certification, in such form as may be specified by the commissioner. Such an application shall include:

(1) assurances satisfactory to the commissioner that the clinic will be operated in accordance with the standards under section 6,

(2) a report to the commissioner identifying the fertility clinics with which the laboratory is associated, and

(3) such other information as the commissioner finds necessary.

(b) The term of a certification issued by the commissioner or an accreditation organization shall be prescribed by the commission-

er and shall be valid for a period of time to be defined by the commissioner through the public comment process. The commissioner shall provide an application for recertification to be submitted at the time of changes in the ownership of a certified embryo laboratory or changes in the administration of such a laboratory. The commissioner shall require payment of fees for certification and recertification in such an amount sufficient to cover the cost to carry out this chapter based on the volume and scope of the services being performed by the embryo laboratories.

Section 8. (a) The commissioner shall conduct inspections of fertility clinics and embryo laboratories to determine if such laboratories meet the requirements established in paragraph (b). Such inspections shall be carried out by the commissioner or by accreditation organizations used by the commissioner under section 6(b).

(b) Inspections shall be:

(l) periodic and unannounced, or

(2) announced in such circumstances as the commissioner determines will not diminish the likelihood of discovering deficiencies in the operations of a laboratory.

Before making a determination under subparagraph (2), the commissioner shall make public, in such a manner as to facilitate comment from any person, a proposal indicating the circumstances under which announced inspections would be permitted.

(c) The specific findings, including deficiencies, identified in an inspection carried out under paragraph (a) and any subsequent corrections to those deficiencies shall be announced and made available to the public upon request beginning no later than sixty days after the date of inspection.

(d) The commissioner may enter and inspect, during regular hours of operation, duly licensed fertility clinics or duly certified embryo laboratories for the purposes of determining whether such a facility is being kept in accordance with the standards set under section 2, in the case of a clinic, or the standards set under section 6, in the case of a laboratory.

(e) In conducting an inspection, the commissioner shall have access to all facilities, equipment, materials, records, and information which the commissioner determines is necessary to determine if the facility so inspected is being operated in accordance with the standards set under this chapter. As part of such inspection, the

commissioner may copy any material, record, or information inspected or require it to be submitted to the commissioner. Such an inspection may be made only upon the presentation of identification to the owner, operator or agent in charge of such laboratory being inspected.

Section 9. (a) The commissioner shall promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories. Such procedures and criteria shall require:

(1) an application to the commissioner by an accreditation organization for approval; and

(2) the submission of such reports and the maintenance of such records as the commissioner may require.

(b) The commissioner shall evaluate the performance of each accreditation organization approved by the commissioner by inspecting under section 8(a) a sufficient number of embryo laboratories accredited by such an organization to allow a reasonable estimate of the performance of such an organization and such other means as the commissioner determines to be appropriate. The commissioner may revoke approval of an accreditation organization if the evaluation carried out hereunder demonstrates to the commissioner that such an organization has failed to comply with its responsibilities under section 8 or for other good cause shown.

(c) If the commissioner revokes approval under paragraph (b) of an accreditation organization after an evaluation under said paragraph, the certification of any embryo laboratory accredited by such organization shall continue in effect for sixty days after the laboratory is notified by the commissioner of the withdrawal of approval; provided, however, that the commissioner may extend the period during which the certification shall remain in effect if the commissioner determines that the laboratory submitted an application to another duly approved accreditation organization for certification after receipt of such notice in a timely manner.

Section 10. (a) A certification issued by the commissioner or accreditation organization for an embryo laboratory shall be revoked or suspended if the commissioner or organization finds, on the basis of inspections and after reasonable notice and oppor-

tunity for hearing to the owner or operator of the laboratory, that the owner or operator or any employee of the laboratory:

(1) has been guilty of misrepresentation in obtaining the certification,

(2) has failed to comply with any of the standards under section 6 applicable to the certification, or

(3) has refused a request of the commissioner or accreditation organization for permission to inspect the laboratory, its operations, its records.

(b) If the certification of an embryo laboratory is revoked or suspended, such certification shall continue in effect for sixty days after the laboratory receives notice of the revocation or suspension. If the certification of an embryo laboratory is revoked or suspended, such laboratory may apply for recertification after one year following the date of the revocation or suspension.

Section 11. (a) Any fertility clinic which has had its license revoked or suspended under section 4 or any embryo laboratory which has had its certification revoked or suspended under section 10 may, after any time within sixty days following the date the action of the commissioner, under either section 4 or section 10, becomes final, file a petition with the Superior Court of the Commonwealth wherein such clinic or such laboratory has its principal place of business for judicial review of such action.

(b) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the commissioner, the court may order such additional evidence. and evidence in rebuttal of such additional evidence, to be taken before the commissioner, and to be adduced upon the hearing in such a manner and upon such terms and conditions as the court may deem appropriate. The commissioner may modify the findings of the commissioner as to the facts, or make new findings, by reason of the additional evidence so taken, and the commissioner shall file such modified or new findings, and the recommendations of the commissioner, if any, for the modification or setting aside of his or her original action, with the return of such additional evidence.

(c) Upon the filing of the petition referred to in paragraph (a), the court shall have jurisdiction to affirm the action or to set it aside, in whole or in part, temporarily or permanently. The findings of the commissioner as to the facts, if supported by substantial evidence, shall be conclusive.

(d) The judgment of the court affirming or setting aside, in whole or in part, any such action of the commissioner shall be final, subject to the review by the supreme judicial court.

Section 12. No fertility clinic which is subject to the licensing requirements under this chapter and no embryo laboratory which is subject to the certification requirements hereunder may perform procedures in such clinic or such laboratory unless said clinic is duly licensed or said laboratory is duly certified. Such a clinic which performs procedures which is not licensed, or such a laboratory which performs procedures which is not certified, in accordance with this chapter, shall be subject to a civil penalty of ten thousand dollars for each violation.

SECTION 2. If any provision within this chapter is deemed to be unconstitutional, then the other provisions shall remain in effect notwithstanding such invalid provisions.

SECTION 3. This chapter shall take effect upon the expiration of one year following its passage.