

**ATTACHMENT A2.**

AUTHORIZING LEGISLATION FCSRCA

102d Congress

An Act

To provide for reporting of pregnancy success rates of assisted reproductive technology programs and for the certification of embryo laboratories.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

## **SECTION 1. SHORT TITLE.**

This Act may be cited as the 'Fertility Clinic Success Rate and Certification Act of 1992'.

## **SEC. 2. ASSISTED REPRODUCTIVE TECHNOLOGY PROGRAMS.**

(a) IN GENERAL- Effective 2 years after the date of the enactment of this Act, each assisted reproductive technology (as defined in section 7) program shall annually report to the Secretary through the Centers for Disease Control--

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

(2) the identity of each embryo laboratory (as defined in section 7) used by such program and whether the laboratory is certified under section 3 or has applied for such certification.

(b) PREGNANCY SUCCESS RATES-

(1) IN GENERAL- For purposes of subsection (a)(1), the Secretary shall, in consultation with the organizations referenced in subsection (c), define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency) during its development.

(2) DEFINITION- In developing the definition of pregnancy success rates, the Secretary shall take into account the effect 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 an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program, and

(B) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of successful oocyte retrieval procedures performed by such program.

(c) CONSULTATION- In developing the definition under subsection (b), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.

## **SEC. 3. CERTIFICATION OF EMBRYO LABORATORIES.**

(a) IN GENERAL-

(1) DEVELOPMENT- Not later than 2 years after the date of the enactment of this Act, the Secretary, through the Centers for Disease Control, shall develop a model program for the certification of embryo laboratories (referred to in this section as a 'certification program') to be carried out by the States.

(2) CONSULTATION- In developing the certification program under paragraph (1), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with the assisted reproductive technology programs.

(b) DISTRIBUTION- The Secretary shall distribute a description of the certification program to--

(1) the Governor of each State,

(2) the presiding officers of each State legislature,

(3) the public health official of each State, and

- (4) the official responsible in each State for the operation of the State's contract with the Secretary under section 1864 of the Social Security Act,  
and shall encourage such officials to assist in the State adopting such program.
- (c) REQUIREMENTS- The certification program shall include the following requirements:
- (1) ADMINISTRATION- The certification program shall be administered by the State and shall provide for the inspection and certification of embryo laboratories in the State by the State or by approved accreditation organizations.
  - (2) APPLICATION REQUIREMENTS- The certification program shall provide for the submission of an application to a State by an embryo laboratory for certification, in such form as may be specified by the State. Such an application shall include--
    - (A) assurances satisfactory to the State that the embryo laboratory will be operated in accordance with the standards under subsection (d),
    - (B) a report to the State identifying the assisted reproductive technology programs with which the laboratory is associated, and
    - (C) such other information as the State finds necessary.An embryo laboratory which meets the requirements of section 353 of the Public Health Service Act shall, for the purposes of subparagraph (A) be considered in compliance with the standards referred to in such subparagraph which are the same as the standards in effect under such section 353.
- (d) STANDARDS- The certification program shall include the following standards developed by the Secretary:
- (1) A standard to assure consistent performance of procedures by each embryo laboratory certified under the certification program or by an approved accreditation organization in a State which has not adopted the certification program.
  - (2) A standard for a quality assurance and a quality control program to assure valid, reliable, and reproducible procedures in the laboratory.
  - (3) A standard for the maintenance of records (on a program by program basis) 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 preventive maintenance, function verification for equipment, and the release of such records to the State upon demand.
  - (5) A standard for the use of such personnel who meet such qualifications as the Secretary may develop.
- (e) CERTIFICATION UNDER STATE PROGRAMS- A State may qualify to adopt the certification program if the State has submitted an application to the Secretary to adopt such program and the Secretary has approved the application. Such an application shall include--
- (1) assurances by the State satisfactory to the Secretary that the certification program within the State meets the requirements of this section,
  - (2) an agreement to make such reports as the Secretary may require, and
  - (3) information about any proposed use of accreditation organizations under subsection (g).
- (f) USE OF ACCREDITATION ORGANIZATIONS- A State which has adopted the certification program may use accreditation organizations approved under section 4 to inspect and certify embryo laboratories.
- (g) INSPECTIONS-
- (1) IN GENERAL- A State which qualifies to adopt the certification program within the State shall conduct inspections in accordance with paragraph (2) to determine if laboratories in the State meet the requirements of such program. Such inspections shall be carried out by the State or by accreditation organizations used by the State under subsection (g).
  - (2) REQUIREMENTS- Inspections carried out under paragraph (1) shall--
    - (A) be periodic and unannounced, or
    - (B) be announced in such circumstances as the Secretary determines will not diminish the likelihood of discovering deficiencies in the operations of a laboratory.

Before making a determination under subparagraph (B), the Secretary shall make public, in such manner as to facilitate comment from any person (including any Federal or other public agency), a proposal indicating the circumstances under which announced inspections would be permitted.

(3) RESULTS- The specific findings, including deficiencies, identified in an inspection carried out under paragraph (1) and any subsequent corrections to those deficiencies shall be announced and made available to the public upon request beginning no later than 60 days after the date of the inspection.

(h) VALIDATION INSPECTIONS-

(1) IN GENERAL- The Secretary may enter and inspect, during regular hours of operation, embryo laboratories--

(A) which have been certified by a State under the certification program, or

(B) which have been certified by an accreditation organization approved by the Secretary under section 4,

for the purpose of determining whether the laboratory is being operated in accordance with the standards in subsection (d).

(2) ACCESS TO FACILITIES AND RECORDS- In conducting an inspection of an embryo laboratory under paragraph (1), the Secretary shall have access to all facilities, equipment, materials, records, and information which the Secretary determines is necessary to determine if such laboratory is being operated in accordance with the standards in subsection (d). As part of such an inspection, the Secretary may copy any material, record, or information inspected or require it to be submitted to the Secretary. Such an inspection may be made only upon the presentation of identification to the owner, operator, or agent in charge of the laboratory being inspected.

(3) FAILURE TO COMPLY- If the Secretary determines as a result of an inspection under paragraph (1) that the embryo laboratory is not in compliance with the standards in subsection (d), the Secretary shall--

(A) notify the State in which the laboratory is located and, if appropriate, the accreditation organization which certified the laboratory,

(B) make available to the public the results of the inspection,

(C) conduct additional inspections of other embryo laboratories under paragraph (1) to determine if--

(i) such State in carrying out the certification program is reliably identifying the deficiencies of such laboratory, or

(ii) the accreditation organization which certified such laboratories is reliably identifying such deficiencies, and

(D) if the Secretary determines--

(i) that such State in carrying out the certification program has not met the requirements applicable to such program, or

(ii) the accreditation organization which certified such laboratory has not met the requirements of section 4,

the Secretary may revoke the approval of the State certification program or revoke the approval of such accreditation organization.

(i) LIMITATION-

(1) SECRETARY- In developing the certification program, the Secretary may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(2) STATE- In adopting the certification program, a State may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(j) TERM- The term of a certification issued by a State or an accreditation organization in a State shall be prescribed by the Secretary in the certification program and shall be valid for a period of time to be defined by the Secretary through the public comment process described in subsection (h)(2). The Secretary shall provide an application for recertification to be submitted at the time of changes in the ownership of a certified laboratory or changes in the administration of such a laboratory.

## **SEC. 4. ACCREDITATION ORGANIZATIONS.**

(a) APPROVAL OF ACCREDITATION ORGANIZATIONS- Not later than 2 years after the date of the enactment of this Act the Secretary, through the Centers for Disease Control, shall promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories. The procedures shall require an application to the Secretary by an accreditation organization for approval. An accreditation organization which has received such an approval--

- (1) may be used by States in the certification program under section 3 to inspect and certify embryo laboratories, or
- (2) may certify embryo laboratories in States which have not adopted such a certification program.

(b) CRITERIA AND PROCEDURES- The criteria and procedures promulgated under subsection (a) shall include--

- (1) requirements for submission of such reports and the maintenance of such records as the Secretary or a State may require, and
- (2) requirements for the conduct of inspections under section 3(h).

(c) EVALUATIONS- The Secretary shall evaluate annually the performance of each accreditation organization approved by the Secretary by--

- (1) inspecting under section 3(i) a sufficient number of embryo laboratories accredited by such an organization to allow a reasonable estimate of the performance of such organization, and
- (2) such other means as the Secretary determines to be appropriate.

(d) TRANSITION- If the Secretary revokes approval under section 3(i)(3)(D) of an accreditation organization after an evaluation under subsection (c), the certification of any embryo laboratory accredited by the organization shall continue in effect for 60 days after the laboratory is notified by the Secretary of the withdrawal of approval, except that the Secretary may extend the period during which the certification shall remain in effect if the Secretary determines that the laboratory submitted an application to another approved accreditation organization for certification after receipt of such notice in a timely manner.

## **SEC. 5. CERTIFICATION REVOCATION AND SUSPENSION.**

(a) IN GENERAL- A certification issued by a State or an accreditation organization for an embryo laboratory shall be revoked or suspended if the State or organization finds, on the basis of inspections and after reasonable notice and opportunity 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 standards under section 3 applicable to the certification, or
- (3) has refused a request of the State or accreditation organization for permission to inspect the laboratory, its operations, and records.

(b) EFFECT- If the certification of an embryo laboratory is revoked or suspended, the certification of the laboratory shall continue in effect for 60 days after the laboratory receives notice of the revocation or suspension. If the certification of an embryo laboratory is revoked or suspended, the laboratory may apply for recertification after one year after the date of the revocation or suspension.

## **SEC. 6. PUBLICATION.**

The Secretary, through the Centers for Disease Control, shall not later than 3 years after the date of the enactment of this Act and annually thereafter publish and distribute to the States and the public--

- (1)(A) pregnancy success rates reported to the Secretary under section 2(a)(1) and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report, and
- (B) from information reported under section 2(a)(2)--
  - (i) the identity of each embryo laboratory in a State which has adopted the certification program under such program and whether such laboratory is certified under section 3,

- (ii) the identity of each embryo laboratory in a State which has not adopted such certification program and which has been certified by an accreditation organization approved by the Secretary under section 4, and
- (iii) in the case of an embryo laboratory which is not certified under section 3 or certified by an accreditation organization approved by the Secretary under section 4, whether the laboratory applied for certification.

## **SEC. 7. FEES.**

The Secretary may require the payment of fees for the purpose of, and in an amount sufficient to cover the cost of, administering this Act. A State operating a program under section 3 may require the payment of fees for the purpose of, and in an amount sufficient to cover the costs of, administering its program.

## **SEC. 8. DEFINITIONS.**

For purposes of this Act:

- (1) ASSISTED REPRODUCTIVE TECHNOLOGY- The term `assisted reproductive technology' means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).
- (2) EMBRYO LABORATORY- The term `embryo laboratory' means a 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.
- (3) SECRETARY- The term `Secretary' means the Secretary of Health and Human Services.

## **SEC. 9. EFFECTIVE DATE.**

This Act shall take effect upon the expiration of 2 years after the date of the enactment of this Act.

Approved October 24, 1992.