HOUSE BILL 2290
By Williams

SENATE BILL 2461

By Bailey

AN ACT to amend Tennessee Code Annotated, Title 4; Title 29; Title 36; Title 63 and Title 68, relative to assisted reproductive technology.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, Part 2, is amended by adding the following as a new section:

63-6-239. Requirements to practice in assisted reproductive technology.

(a) The board, in collaboration with the board of osteopathic examination, shall establish requirements for a person licensed pursuant to this chapter to obtain a certificate to practice in assisted reproductive technology.

(b) The board shall issue a certificate to a person licensed pursuant to this chapter who meets the requirements established by the board to practice in assisted reproductive technology.

(c) As used in this section:

(1) "Assisted reproductive technology" has the same meaning as defined in 42 U.S.C. § 263a-7; and

(2) "Board" means the board of medical examiners.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding the following as a new part:

63-6-1401. Part definitions.

As used in this part:

(1) "Assisted reproductive technology" has the same meaning as defined in 42 U.S.C. § 263a-7;

(2) "Board" means the board of medical examiners; and

(3) "Certified assisted reproductive technologist" means a person certified to practice in assisted reproductive technology pursuant to this part.

63-6-1402. Practice in assisted reproductive technology.

(a) A person is prohibited from practicing in assisted reproductive technology unless the person has obtained an assisted reproductive technology certificate from the board pursuant to § 63-6-239.

(b) A person may practice in assisted reproductive technology if:

(1) The board has approved the person's application to practice medicine or surgery, as described in § 63-6-207; and

(2) The board determines the person has met the requirements established pursuant to § 63-6-239 to receive a certificate to practice in assisted reproductive technology.

(c) Notwithstanding subsection (a), a certified assisted reproductive technologist may delegate tasks in the practice of assisted reproductive technology to a person who is licensed pursuant to chapter 7 or 19 of this title or a person holding a training license or exemption pursuant to the rules promulgated by the board of medical examiners as long as the task is within the person's training and scope of practice.

63-6-1403. Compliance required.

A certified assisted reproductive technologist must be in compliance with this part within sixty (60) days after the rules become effective to utilize assisted reproductive technology.

63-6-1404. Prohibitions on genetic testing.

A certified assisted reproductive technologist is prohibited from genetically testing an embryo unless the genetic test is for chromosomal abnormality or fatal fetal anomaly.

63-6-1405. Affidavit required - Consent forms.

(a) A certified assisted reproductive technologist shall affirm by affidavit to the board that such technologist uses the standard Society for Assisted Reproductive Technology (SART) template consent form.

(b) In addition to the SART consent form, the certified assisted reproductive technologist must include in the consent form to a prospective patient the following:

(1) A statement that the certified assisted reproductive technologist is prohibited from genetically testing an embryo unless the genetic test is for chromosomal abnormality or fatal fetal anomaly; and

(2) Confirmation from the prospective patient that such patient has a clear understanding of and provides informed consent regarding the custodial care of an unused or abandoned embryo.

63-6-1406. Rules.

The board is authorized to promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 3. Tennessee Code Annotated, Title 63, Chapter 9, Part 1, is amended by adding the following as a new section:

63-9-114. Requirements to practice in assisted reproductive technology.

(a) The board, in collaboration with the board of medical examiners, shall establish requirements for a person licensed pursuant to this chapter to obtain a certificate to practice in assisted reproductive technology.

(b) The board shall issue a certificate to a person licensed pursuant to this chapter who meets the requirements established by the board to practice in assisted reproductive technology.

(c) As used in this section:

(1) "Assisted reproductive technology" has the same meaning as defined in 42 U.S.C. § 263a-7; and

(2) "Board" means the board of osteopathic examination.

SECTION 4. Tennessee Code Annotated, Title 63, Chapter 9, is amended by adding the following as a new part:

63-9-201. Part definitions.

As used in this part:

(1) "Assisted reproductive technology" has the same meaning as defined in 42 U.S.C. § 263a-7;

(2) "Board" means the board of osteopathic examination; and

(3) "Certified assisted reproductive technologist" means a person certified to practice assisted reproductive technology pursuant to this part.

63-9-202. Practice in assisted reproductive technology.

(a) A person is prohibited from practicing in assisted reproductive technology unless the person has obtained an assisted reproductive technology certificate from the board pursuant to § 63-9-114.

(b) A person may practice in assisted reproductive technology if:

(1) The board has approved the person's application to practice osteopathic medicine, as described in § 63-9-104; and

(2) The board determines the person has met the requirements established pursuant to § 63-9-114 to receive a certificate to practice in assisted reproductive technology.

(c) Notwithstanding subsection (a), a certified assisted reproductive technologist may delegate tasks in the practice of assisted reproductive technology to a person who

is licensed pursuant to chapter 7 or 19 of this title or a person holding a training license or exemption pursuant to the rules promulgated by the board of osteopathic examination as long as the task is within the person's training and scope of practice.

63-9-203. Compliance.

A certified assisted reproductive technologist must be in compliance with this part within sixty (60) days after the rules become effective to use assisted reproductive technology.

63-9-204. Prohibitions on genetic testing.

A certified assisted reproductive technologist is prohibited from genetically testing an embryo unless the genetic test is for chromosomal abnormality or fatal fetal anomaly.

63-9-205. Affidavit - Consent forms.

(a) A certified assisted reproductive technologist shall affirm by affidavit to the board that the person uses the standard Society for Assisted Reproductive Technology (SART) template consent form.

(b) In addition to the SART consent form, the certified assisted reproductive technologist must include in the consent form to a prospective patient the following:

(1) A statement that the certified assisted reproductive technologist is prohibited from genetically testing an embryo unless the genetic test is for chromosomal abnormality or fatal fetal anomaly; and

(2) Confirmation from the prospective patient that such patient has a clear understanding of and provides informed consent regarding the custodial care of an unused or abandoned embryo.

63-9-206. Rules.

The board is authorized to promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 5. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following as a new part:

68-1-2101. Part definitions.

As used in this part:

(1) "Assisted reproductive technology" has the same meaning as defined in 42 U.S.C. § 263a-7;

(2) "Department" means the department of health; and

(3) "Fertility clinic" means:

(A) A location that is considered an embryo laboratory, as defined in 42 U.S.C. § 263a-7;

(B) A location where a person is practicing assisted reproductive technology; or

(C) A location where a person is engaging in the storage of embryos.

68-1-2102. Certification required - Compliance.

(a) Each fertility clinic operating in this state shall obtain a certificate to utilize assisted reproductive technology.

(b) A fertility clinic must renew the clinic's certification at intervals determined by the department.

(c) A fertility clinic must be in compliance with this part within sixty (60) days after the rules become effective to utilize assisted reproductive technology.

68-1-2103. Certification for fertility clinics - Inspections - Authority.

(a) The department shall:

(1) Create a certification for fertility clinics in this state to utilize assisted reproductive technology;

(2) Create requirements for the utilization of assisted reproductive technology for fertility clinics; and

(3) Conduct an annual inspection of each fertility clinic.

(b) For purposes of an inspection pursuant to subdivision (a)(3), each fertility clinic shall provide the department access to any facilities, equipment, materials, records, and information that the department determines has a bearing on whether the fertility clinic is operating in accordance with this part.

(c) The department has the authority to:

(1) Deny a fertility clinic's application for a certification to utilize assisted reproductive technology;

(2) Suspend, limit, or restrict a previously certified fertility clinic for a time and in a manner as determined by the department;

(3) Permanently revoke a fertility clinic's certification; or

(4) Refuse to renew a fertility clinic's certification.

(d) The department is authorized to adopt rules to effectuate this part, including creating and establishing application requirements, fees, and standards for such certification and grounds for denying, suspending, revoking, or refusing to renew a certification. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

68-1-2104. Bond requirement.

(a) A fertility clinic shall post a bond in an amount as determined by the commissioner of health for the storage of embryos.

(b) Each certification renewal application must be accompanied by proof of such bond.

68-1-2105. Reporting requirement.

(a) On or before January 31 of each year, the medical director of each fertility clinic located in this state shall:

(1) Submit a report to the federal centers for disease control and prevention (CDC) detailing the pregnancy success rates achieved by the fertility clinic through the utilization of assisted reproductive technology from the prior calendar year; and

(2) Report to the department the pregnancy success rates achieved by the fertility clinic through the utilization of assisted reproductive technology from the prior calendar year and an affirmation that the fertility clinic submitted the report as described in subdivision (a)(1) to the CDC.

(b) If a medical director fails to submit the report to the department pursuant to subsection (a), then the fertility clinic may be subject to disciplinary action by the department, which may include the suspension of the clinic's certification to utilize assisted reproductive technology.

68-1-2106. Rules.

The department is authorized to promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 6. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 7. For the purposes of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect July 1, 2026, the public welfare requiring it.

Senate Health and Welfare 2

Amendment No. 2 to SB2461

Crowe
Signature of Sponsor

AMEND Senate Bill No. 2461* House Bill No. 2290

by deleting all language after the caption and substituting:

WHEREAS, the Society for Assisted Reproductive Technology membership is the "gold standard" for clinics providing assisted reproductive technology; and

WHEREAS, the Society for Assisted Reproductive Technology is a standard that ensures an abundance of regulation; and

WHEREAS, the Society for Assisted Reproductive Technology clinics are committed to the highest quality standards of care; and

WHEREAS, all Society for Assisted Reproductive Technology clinics are required to advertise truthfully; and

WHEREAS, all Society for Assisted Reproductive Technology clinics accurately report outcomes so that patients can trust their provider; and

WHEREAS, all Society for Assisted Reproductive Technology clinics work with nationally accredited laboratories to assure the best possible reproductive environments; and

WHEREAS, the Society for Assisted Reproductive Technology requires:

(a) Annual submission of cycle-specific clinic outcome data to the Society for Assisted Reproductive Technology Registry, verified by the medical director, with permission to disclose such data to the public and to allow data to be validated. Approximately eight to ten percent of reporting clinics are validated each year;

(b) Accreditation of an embryology laboratory occurs every two years by either the College of American Pathologists or Joint Commission on Accreditation of Healthcare Organizations;

(c) The medical director of any new practice must be reproductive endocrinology and infertility (REI) subspecialty certified by the American Board of Obstetrics and Gynecology, an active candidate for subspecialty certification, or grandfathered in by having been a medical director of a Society for Assisted Reproductive Technology member practice prior to January 1, 2000;

(d) All assisted reproductive technology laboratory directors to meet uniform criteria and physicians not currently laboratory directors to complete the reproductive endocrinology fellowship training in the laboratory director track, attain sufficient hands-on experience to meet American Society of Reproductive Medicine/Society for Assisted Reproductive Technology guidelines and pass a certification exam administered by the American Board of Bioanalysis;

(e) Adherence to all American Society of Reproductive Medicine/Society for Assisted Reproductive Technology guidelines, including ethical, practice, advertising, and laboratory; and

(f) Fulfillment of all financial obligations regarding dues and fees; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following as a new part:

68-1-2101. Part definitions.

As used in this part:

(1) "Assisted reproductive technology" or "ART" has the same meaning as defined in 42 U.S.C. § 263a-7;

(2) "Department" means the department of health;

(3) "Fertility clinic" means:

(A) A location that is considered an embryo laboratory, as defined in 42 U.S.C. § 263a-7;

(B) A location where a person is practicing assisted reproductive

technology; or

(C) A location where a person is engaging in the storage of embryos; and

(4) "Society for Assisted Reproductive Technology" or "SART" means a United States-based professional organization that sets clinical and laboratory standards for assisted reproductive technology, collects and publishes invitro fertilization success rate data from member clinics, provides patient education, provides professional guidance, and works closely with the federal centers for disease control and prevention on ART data reporting.

68-1-2102. Certification required.

(a) Each fertility clinic operating in this state shall obtain a certificate to perform assisted reproductive technology services.

(b) The department shall issue a certificate to a fertility clinic that has submitted the following to the department biennially:

(1) Verification of the fertility clinic's SART membership;

(2) An emergency plan for the transfer of embryos should the clinic close permanently for any reason; and

(3) Proof of passing the most recent laboratory inspection from either the College of American Pathologists or the Joint Commission on Accreditation of Healthcare Organizations.

68-1-2103. Clinical directors.

For a fertility clinic to operate in this state, the clinical director must:

(1) Be licensed to practice medicine or osteopathic medicine pursuant to title 63, chapter 6 or 9;

(2) Be board certified in obstetrics and gynecology by a member board of the American Board of Medical Specialties;

(3) Have successfully completed a fellowship in reproductive

endocrinology and infertility accredited by the Accreditation Council for Graduate Medical Education or possess equivalent training and experience;

(4) Demonstrate substantial clinical experience in assisted reproductive technology procedures; and

(5) Maintain continuing medical education relevant to reproductive endocrinology, infertility, and assisted reproductive technology.

68-1-2104. Rules.

The department may promulgate rules only as necessary to effectuate this part. The rules must not be inconsistent with this act and must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. For the purposes of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect January 1, 2027, the public welfare requiring it.

Amendment No. 1 to HB2290

Terry
Signature of Sponsor

AMEND Senate Bill No. 2461* House Bill No. 2290

by deleting all language after the caption and substituting:

WHEREAS, the Society for Assisted Reproductive Technology membership is the "gold standard" for clinics providing assisted reproductive technology; and

WHEREAS, the Society for Assisted Reproductive Technology is a standard that ensures an abundance of regulation; and

WHEREAS, the Society for Assisted Reproductive Technology clinics are committed to the highest quality standards of care; and

WHEREAS, all Society for Assisted Reproductive Technology clinics are required to advertise truthfully; and

WHEREAS, all Society for Assisted Reproductive Technology clinics accurately report outcomes so that patients can trust their provider; and

WHEREAS, all Society for Assisted Reproductive Technology clinics work with nationally accredited laboratories to assure the best possible reproductive environments; and

WHEREAS, the Society for Assisted Reproductive Technology requires:

(a) Annual submission of cycle-specific clinic outcome data to the Society for Assisted Reproductive Technology Registry, verified by the medical director, with permission to disclose such data to the public and to allow data to be validated. Approximately eight to ten percent of reporting clinics are validated each year;

(b) Accreditation of an embryology laboratory occurs every two years by either the College of American Pathologists or Joint Commission on Accreditation of Healthcare Organizations;

(c) The medical director of any new practice must be reproductive endocrinology and infertility (REI) subspecialty certified by the American Board of Obstetrics and Gynecology, an active candidate for subspecialty certification, or grandfathered in by having been a medical director of a Society for Assisted Reproductive Technology member practice prior to January 1, 2000;

(d) All assisted reproductive technology laboratory directors to meet uniform criteria and physicians not currently laboratory directors to complete the reproductive endocrinology fellowship training in the laboratory director track, attain sufficient hands-on experience to meet American Society of Reproductive Medicine/Society for Assisted Reproductive Technology guidelines and pass a certification exam administered by the American Board of Bioanalysis;

(e) Adherence to all American Society of Reproductive Medicine/Society for Assisted Reproductive Technology guidelines, including ethical, practice, advertising, and laboratory; and

(f) Fulfillment of all financial obligations regarding dues and fees; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 68, Chapter 1, is amended by adding the following as a new part:

68-1-2101. Part definitions.

As used in this part:

(1) "Assisted reproductive technology" or "ART" has the same meaning as defined in 42 U.S.C. § 263a-7;

(2) "Department" means the department of health;

(3) "Fertility clinic" means:

(A) A location that is considered an embryo laboratory, as defined in 42 U.S.C. § 263a-7;

(B) A location where a person is practicing assisted reproductive

technology; or

(C) A location where a person is engaging in the storage of embryos; and

(4) "Society for Assisted Reproductive Technology" or "SART" means a United States-based professional organization that sets clinical and laboratory standards for assisted reproductive technology, collects and publishes invitro fertilization success rate data from member clinics, provides patient education, provides professional guidance, and works closely with the federal centers for disease control and prevention on ART data reporting.

68-1-2102. Certification required.

(a) Each fertility clinic operating in this state shall obtain a certificate to perform assisted reproductive technology services.

(b) To receive a certificate from the department, a fertility clinic must submit the following to the department biennially:

(1) Verification of the fertility clinic's membership in SART or an equivalent organization subject to the approval of the department;

(2) An emergency plan for the transfer of embryos should the clinic close permanently for any reason; and

(3) Proof of passing the most recent laboratory inspection from either the College of American Pathologists or the Joint Commission on Accreditation of Healthcare Organizations.

68-1-2103. Clinical directors.

For a fertility clinic to operate in this state, the clinical director must:

(1) Be licensed to practice medicine or osteopathic medicine pursuant to title 63, chapter 6 or 9;

(2) Be board certified in obstetrics and gynecology by a member board of the American Board of Medical Specialties;

(3) Have successfully completed a fellowship in reproductive endocrinology and infertility accredited by the Accreditation Council for Graduate Medical Education or possess equivalent training and experience;

(4) Demonstrate substantial clinical experience in assisted reproductive technology procedures; and

(5) Maintain continuing medical education relevant to reproductive endocrinology, infertility, and assisted reproductive technology.

68-1-2104. Genetic testing.

(a) The general assembly recognizes the importance of adherence to evidence-based best practices in the provision of genetic testing services in connection with assisted reproductive technology. Fertility clinics shall follow current clinical practice guidelines and professional standards for genetic testing issued by nationally recognized professional societies or organizations in the field of reproductive medicine or obstetrics and gynecology.

(b) This section does not require compliance with any specific guideline, create a private cause of action, establish a standard of care, or serve as a basis for liability.

68-1-2105. Rules.

The department may promulgate rules to effectuate this part. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

SECTION 2. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. For the purposes of promulgating rules, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect January 1, 2027, the public welfare requiring it.

Amendment No. 2 to HB2290

Clemmons
Signature of Sponsor

AMEND Senate Bill No. 2461* House Bill No. 2290

by deleting "To receive a certificate from the department, a fertility clinic must submit the following to the department biennially" in § 68-1-2102(b) in SECTION 1 and substituting "The department shall issue a certificate to a fertility clinic that submits the following to the department biennially".