WEST VIRGINIA LEGISLATURE

2024 REGULAR SESSION

Introduced

House Bill 5054

By Delegates Summers and Tully

[Introduced January 23, 2024; Referred to the Committee on Health and Human Resources then Government Organization]

A BILL to amend and reenact §16-2E-1, §16-2E-2, §16-2E-3, §16-2E-4, and §16-2E-5 of the Code of West Virginia, 1931, as amended; and to amend said code by adding thereto six new sections, designated §16-2E-6, §16-2E-7, §16-2E-8, §16-2E-9, §16-2E-10, and §16-2E-11, all relating to the licensure of birthing centers; defining terms; creating license types for birthing centers; updating the procedure for application for and obtaining a license; updating license fees; providing for regulation by the Office of Health Facility Licensure and Certification; designating the necessity for a governing body and administrator and prescribing the duties and responsibilities for the same; setting certain minimum standards in any birthing center; setting certain minimum required services and prohibited services in any birthing center; restricting the location of birthing centers; allowing for variances and waivers from licensure standards; providing for inspections and inspection warrants; designating license limitations; providing procedure for denial, suspension, or revocation of a license; allowing civil money penalties; providing for administrative review and appeal rights; prescribing advertisement disclosure; and permitting the Inspector General to promulgate rules, including emergency rules.

Be it enacted by the Legislature of West Virginia:

article 2E. Birthing Centers.

§16-2E-1. ~~Definitions.~~ Purpose.

~~For the purpose of this article:~~

~~"Birthing center" means a type of facility which is a building, house or the equivalent to provide facilities and staff to support a birthing service for pregnant clients~~

The purpose of this act is to establish licensing requirements for birthing centers to ensure that patients may be lawfully treated in accordance with best practices and facilities meet minimum practice and oversight requirements developed by the Office of Inspector General. The Legislature recognizes the need for health care facilities for childbirth where care is provided in the midwifery and wellness model.

§16-2E-2. ~~Birthing centers to obtain license; application; fees; suspension or revocation~~

Definitions.

~~No person, partnership, association or corporation, or any local governmental unit or any division, department, board or agency thereof may operate a birthing center unless such operation shall have been approved and licensed by the state director of health in accordance with the provisions of this article and the rules and regulations lawfully promulgated hereunder provided that all birthing centers which are in operation or which have received a certificate of need valid as of the date of passage of this act shall be deemed to have been so approved and shall be issued a license within thirty days of passage of this act.~~

~~Any person, partnership, association or corporation, or any local governmental unit or any division, department, board or agency thereof desiring a license hereunder shall file with the department of health an application in such form as the department shall prescribe and furnish accompanied by a fee of ten dollars. Information received by the department of health under the provisions of this section shall be confidential. The director of health is authorized to issue licenses for the operation of birthing centers which are found to comply with the provisions of this article and with all rules and regulations promulgated by the department. The license issued shall not be transferred or assignable. The director of health is authorized to suspend or revoke a license issued hereunder if the provisions of this article or of the rules and regulations are violated.~~

~~Before any such license is suspended or revoked, however, written notice shall be given the licensee, stating the grounds of the complaint, and the date, time and place set for the hearing on the complaint, which date shall not be less than thirty days from the time notice is given. Such notice shall be sent by registered mail to the licensee at the address where the institution concerned is located. The licensee shall be entitled to be represented by legal counsel at the hearing.~~

~~If a license is revoked as herein provided, a new application for a license shall be considered by the director of health if, when and after, the conditions upon which revocation was based have been corrected and evidence of this fact has been furnished. A new license shall then be granted after proper inspection has been made and all provisions of this article and rules and regulations promulgated hereunder have been satisfied.~~

~~All of the pertinent provisions of article five, chapter twenty-nine-A of this Code shall apply to and govern any hearing authorized and required by the provisions of this article and the administrative procedure in connection with and following any such hearing, with like effect as if the provisions of said article five were set forth in extenso in this section.~~

~~The court shall have the power to affirm, modify, or reverse the decision of the department and either the applicant or licensee or the department may appeal from the court’s decision to the supreme court of appeals. Pending the final disposition of the matter the status quo of the applicant or licensee shall be preserved.~~

~~Any applicant or licensee who is dissatisfied with the decision of the state department of health as a result of the hearing provided in this section may, within thirty days after receiving notice of the decision, appeal to the circuit court, in term or in vacation, of the county in which the applicant or licensee is located for judicial review of the decision.~~

"Administrator" means the person who is responsible for advising and consulting with the clinical staff of a birthing center on all matters related to the clinical management of all patients, irrespective of the person's assigned title and who is directly responsible for the general operation and administration of the birthing center. The administrator has the responsibility for implementing policies and procedures and administrative operation of the birthing center.

"Birthing center" means a facility licensed for the primary purpose of providing midwifery care, low-risk deliveries, and newborn care immediately after delivery, for a stay of generally less than twenty-four hours. This term does not include a hospital, ambulatory surgical center, or the resident of the patient giving birth. A birthing center may be a location for additional services in shared or adjacent spaces, including outpatient gynecologic care, primary care, and education and support services within each Licensed Provider's scope of practice.

"Director" means the Director of the Office of Health Facility Licensure and Certification, or his or her designee.

"Governing body" means the individual, agency, group, or corporation, appointed, elected, or otherwise designated, who is ultimately responsible for and has authority over the conduct and regulatory compliance of the birthing center.

"Inspector General" means the Inspector General of the Office of the Inspector General, as described in subsection §16-1-22 of this code, or his or her designee.

"Office of Health Facility Licensure and Certification" means the West Virginia Office of Health Facility Licensure and Certification within the Office of Inspector General.

"Substantial compliance" means a level of compliance with the minimum standards set forth in this article and any applicable rules promulgated pursuant to this article so as not to impose a risk to the rights, health, and safety of a patient.

"Variance" means written permission granted by the Inspector General to a birthing center that a requirement of this article or rules promulgated pursuant to this article may be accomplished in manner different from the manner set forth in this article or associated rule.

"Waiver" means a formal, time-limited agreement between the Inspector General and the birthing center that suspends a rule, policy, or standard for a specific situation so long as the health and safety of patients is better served in the situation by suspension of the rule, policy, or standard that by enforcement.

§16-2E-3. ~~State director of health to establish rules and regulations; legislative findings; emergency filing~~ Birthing Centers to obtain license; applications; fees and inspections.

~~The director of health shall promulgate rules and regulations not in conflict with any provision of this article, as it finds necessary in order to ensure adequate care and accommodations for consumers of birthing centers. In promulgating such regulations the director shall be limited to simple, necessary provisions which shall not have the effect of hampering the development and licensure of birthing centers. Such regulations shall not address acceptable site characteristics such as the number of minutes of travel time between a birthing center and a hospital, or physical environment, such as acceptable levels of temperature of any refrigerator found in a birthing center, or clinical equipment, such as the number and kind of clocks which a birthing center must have on the premises. Such regulations shall require that all birthing centers submit satisfactory evidence that the center has implemented the paternity program created pursuant to section thirteen of this article along with any application for licensure.~~

~~The Legislature hereby finds and declares that it is in the public interest to encourage the development of birthing centers for the purpose of providing an alternative method of birth and therefore, in order to provide for the licensing of such birthing centers to prevent substantial harm to the public interest because of preexisting delay, within sixty days of passage of this article, the director of health shall proceed to promulgate such rules and regulations under the provisions of section fifteen, article three, chapter twenty-nine-a of this code.~~

(a) This Inspector General designates the director of the Office of Health Facility Licensure and Certification to enforce the provisions of this article, except where otherwise stated.

(b) No person, partnership, association, or corporation may operate a birthing center without first obtaining a license from the director in accordance with the provisions of this article and the rules lawfully promulgated pursuant to this article.

(c) Any person, partnership, association, or corporation desiring a license to operate a birthing center in this state shall file with the Office of Health Facility Licensure and Certification an application in such form and with such information as the director shall prescribe and furnish accompanied by an application fee.

(d) The Office of Health Facility Licensure and Certification shall inspect each facility and review all documentation submitted with the application. The director shall issue a license if the facility is in substantial compliance with the provisions of this article and with any rules lawfully promulgated pursuant to this article.

(e) A license shall be issued in one of three categories:

(1) An initial six month license shall be issued to a birthing center establishing a new facility for which there is insufficient patient participation to demonstrate substantial compliance with this article and with all rules promulgated pursuant to this article.

(2) A provisional license shall be issued when a birthing center seeks a renewal license, and the birthing center is not in substantial compliance with this article and with all rules promulgated pursuant to this article but does not pose a significant risk to the rights, health, and safety of a consumer. It shall expire not more than six months from the date of issuance, and may not be consecutively reissued; or

(3) A renewal license shall be issued when a birthing center is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal license shall expire not more than one year from the date of issuance.

(f) At least 60 days prior to the license expiration date, an application for renewal shall be submitted by the birthing center to the director on forms furnished by the director. A license shall be renewed if the director determines that the applicant is in substantial compliance with this article and with all rules promulgated pursuant to this article.

(g) A license issued to one facility location pursuant to this article is not transferrable or assignable. Any change of ownership of a licensed birthing center requires submission of a new application. The birthing center shall notify the Office of Health Facility Licensure and Certification of any change in ownership within 10 days of the change and must submit a new application within the time frame prescribed by the director.

(h) Any person, partnership, association, or corporation that seeks to obtain or renew a license for a birthing center in this state must submit to the director the following information and documentation:

(1) Full operating name of the birthing center as advertised;

(2) Legal name of the birthing center as registered with the West Virginia Secretary of State;

(3) Physical address of the birthing center;

(4) Preferred mailing address for the birthing center;

(5) Email address to be used as the primary contact for the birthing center;

(6) Federal Employer Identification Number assigned to the birthing center;

(7) All business licenses issued to the birthing center by this state, the State Tax Department, the Secretary of State, and all other applicable business entities;

(8) Brief description of all services provided by the birthing center;

(9) Hours of operation;

(10) Legal Registered Owner Name – name of the person registered as the legal owner of the birthing center. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;

(11) Administrator's full name, professional license number, and a list of all current certifications;

(12) Name and location address of all birthing centers owned or operated by the applicant;

(13) Notarized signature of applicant; and

(14) Check or money order for licensing fee and inspection fee.

(i) Upon satisfaction that an applicant has met all of the requirements of this article, the director shall issue a license to operate a birthing center.

(j) The birthing center shall display the current license in a prominent location where services are provided and in clear view of all patients.

(k) The schedule of fees for a birthing center license is as follows:

(1) Initial licensure fee is $125;

(2) First renewal licensure fee is $125;

(3) Second and all subsequent renewal licensure fee is $250; and

(4) Change of Ownership licensure fee is $250.

(l) In addition to set fee, the annual renewal fee shall be adjusted on the first day of June of each year to correspond with the increases in the consumer price index. The Office of Health Facility Licensure and Certification shall post the consumer price index increases, immediately after those increases are released annually, on its website located at: <http://ohflac.wvdhhr.org/>.

(m) An application for licensure is not considered complete until the applicant pays the licensing and inspection fee. The fee shall accompany the application form.

(n) License fees paid by an applicant are non-refundable.

(o) The director shall inspect on a periodic basis all birthing centers that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.

§16-2E-4. ~~Insurance~~ Operational Requirements.

~~Not later than the first day of July, one thousand nine hundred eighty-three, every policy or contract of individual accident and sickness insurance covered under the provisions of article fifteen, chapter thirty-three, or policy or contract of group accident and sickness insurance covered under the provisions of article sixteen of said chapter, including, but not limited to, any subscriber contract issued by a corporation organized pursuant to article twenty-four of said chapter, shall include benefits to all subscribers and members for birthing center service charges, and for care rendered therein by a licensed nurse midwife or midwife as this occupation is defined in section one, article fifteen, chapter fifty of this Code, and which care is within the scope of duties for such licensed nurse midwife or midwife as permitted by the provisions of section seven, article fifteen of said chapter thirty~~

(a) The birthing center shall be licensed and registered in this state with the director, the Secretary of State, the State Tax Department, and all other applicable business or licensing entities.

(b) Each birthing center shall identify the governing body. The governing body shall be responsible for appointing the administrator. The governing body shall be responsible for monitoring and ensuring compliance with all requirements related to the licensing of the birthing center. The governing body shall adopt written policies and procedures for the operation of this birthing center in accordance with this article and any rules promulgated pursuant thereto.

(c) Each birthing center shall designate an administrator. The administrator shall be responsible for the daily operation of the birthing center, as further specified in the rules promulgated pursuant to this article. The administrator may delegate the day-to-day operation of a birthing center as provided in rules promulgated pursuant to this article. Within 10 days after termination of a administrator, the governing body shall notify the director of the identity of another administrator for that birthing center. Failure to have an administrator practicing at the birthing center may be the basis for a suspension or revocation of the birthing center license. The administrator shall:

(1) Have a full, active, and unencumbered license to practice and provide services and treatment within his or her scope of practice, including, but not limited to, preconception, prenatal, labor, birth, and postpartum care and early care of the newborn and who may be the primary attendant during the prenatal period;

(2) Practice at the licensed birthing center a sufficient number of hours to carry out those duties specifically assigned to the administrator as further described in the rules promulgated pursuant to this article;

(3) Be responsible for monitoring and ensuring compliance with all and operation of the birthing center;

(4) Supervise, control, and direct the activities of each individual working or operating at the birthing center including any employee, volunteer, or individual under contract, who provides treatment at the birthing center or is associated with the provision of that treatment. The supervision, control, and direction shall be provided in accordance with rules promulgated by the Inspector General; and

(5) Complete other requirements prescribed by the Inspector General by rule.

(d) The birthing center shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a patient for any treatment, a birthing center must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: *Provided*, That the director, in consultation with the Inspector General, may grant a variance from this requirement pursuant to §16-2E-5 of this code. The birthing center shall also document whether a patient has no insurance. At the option of the birthing center, treatment may commence prior to billing.

(e) All persons employed by the birthing center shall comply with the requirements for the operation of a birthing center established within this article or by any rule adopted pursuant to this article.

(f) All employees of a birthing center shall furnish fingerprints for a state and federal criminal records check by the Criminal Identification Bureau of the West Virginia State Police and the Federal Bureau of Investigation. The fingerprints shall be accompanied by a signed authorization for the release of information and retention of the fingerprints by the Criminal Identification Bureau and the Federal Bureau of Investigation. The birthing center shall be subject to the provisions of § 16-49-1 *et seq*. of this code and subsequent rules promulgated thereunder.

(g) A birthing center shall comply with:

(1) The West Virginia Board of Pharmacy regulations;

(2) Any applicable professional licensing agencies for any and all staff or employees of the birthing center;

(3) Any requirements as specified in the rules promulgated pursuant to this article.

(h) Birthing centers shall provide care and treatment in a home-like environment with adequate space for furnishings, equipment, supplies, and comfortable accommodations for patients and families served. The birthing center shall provide services, including, but not limited to, initial and ongoing risk and patient eligibility assessments; intrapartum care; postpartum care; and laboratory services, as further described in the rules promulgated pursuant to this article.

(i) The following limitations apply to the services performed at birthing centers:

(1) The use of general or regional anesthesia, including epidurals, is prohibited;

(2) Notwithstanding paragraph (a), systemic analgesia, nitrous oxide, and other forms of pain relief may be administered at the birthing center if it is performed within the provider's scope of practice, and as determined by the birthing center's policies and procedures;

(3) Labor shall not be induced, stimulated, or augmented with pharmacologic agents during the first or second stages of labor or before labor;

(4) Surgical services must be limited to those normally performed during an uncomplicated birth, including episiotomy and repair. No operative obstetrics or cesarean sections shall be performed;

(5) The use of vacuum extractors, vaginal forceps, or continuous electronic fetal monitoring is prohibited; and

(6) The risk factors preclude a patient from delivering at the birthing center:

(A) Known breech or non vortex presentation at time of admission;

(B) Multiple gestation, such as twins;

(C) Gestation less than 36 weeks and zero days, or greater than 42 weeks and zero days; and

(D) Other risk factors contrary to the birthing center's established risk criteria.

(j) Each birthing center location shall be licensed separately, regardless of whether the center is operated under the same business name or management as another birthing center.

(k) The birthing center shall report information, data, statistics, and other information as directed in this code, and the rules promulgated pursuant to this article, to required agencies and other authorities.

(l) The birthing center shall immediately notify the director, or his or her designee, in writing of any changes to its operations that affect the birthing center's continued compliance with the certification and licensure requirements.

§16-2E-5. ~~Violations; penalties; injunction~~ Restrictions; variances and waivers.

~~Any person, partnership, association or corporation, and any local governmental unit or any division, department, board or agency thereof establishing, conducting, managing, or operating a birthing center without first obtaining a license therefor as herein provided, or violating any provisions of this article or any rule or regulation lawfully promulgated thereunder, shall be guilty of a misdemeanor, and, upon conviction thereof, shall be punished for the first offense by a fine of not more than one hundred dollars, or by imprisonment in the county jail for a period of not more than ninety days, or by both such fine and imprisonment, in the discretion of the court. For each subsequent offense the fine may be increased to not more than five hundred dollars, with imprisonment in the county jail for a period of not more than ninety days, or both such fine and imprisonment, in the discretion of the court. Each day of continuing violation after conviction shall be considered a separate offense.~~

~~Notwithstanding the existence or pursuit of any other remedy, the director may, in the manner provided by law, maintain an action in the name of the State for an injunction against any person, partnership, association, corporation, or any local governmental unit, or any division, department, board or agency thereof, to restrain or prevent the establishment, conduct, management, or operation of any birthing center without first obtaining a license therefor in the manner hereinbefore provided.~~

(a) A birthing center shall not be located or operated within a hospital licensed and defined in §16-5B-1 *et seq.* of this code is located. Birthing centers are defined as freestanding facilities which provide healthcare as specified in this article and in the rules promulgated pursuant to this article in a home-like environment, which is different and outside of the hospital setting, while promoting safety and quality care for patients and newborn infants.

(b) Birthing centers shall not have procedures for offering a bounty, monetary, equipment or merchandise reward, or free services for individuals in exchange for recruitment of new patients into the birthing center.

(c) The director, in consultation with the Inspector General, may grant a waiver or a variance from any licensure standard, or portion thereof, for the period which the license is in effect.

(1) Requests for waivers or variances of licensure standards shall be in writing to the director and shall include:

(A) The specific section of this article or rules promulgated pursuant to this article for which a waiver or variance is sought;

(B) The rationale for requesting the waiver or variance;

(C) Documentation by the birthing center's administrator or governing body to the director that describes how the birthing center will maintain the quality of services and patient safety and rights if the waiver or variance is granted; and

(D) The consequences of not receiving approval of the requested waiver or variance.

(2) The director, in consultation with the Inspector General, shall issue a written statement to the birthing center granting or denying a request for a waiver or variance of birthing center licensure standards.

(3) The birthing center shall maintain a file copy of all requests for waivers or variances and the approval or denial of the requests for the period during which the license is in effect.

(4) The Office of Health Facility Licensure and Certification may inspect each birthing center prior to a waiver or variance being granted, including a review of patient records, to ensure and verify that any waiver or variance request meets the spirit and purpose of this article and the rules promulgated pursuant to this article. The Office of Health Facility Licensure and Certification may verify, by unannounced inspection, that the birthing center is in compliance with any waiver or variance granted by the director, in consultation with the Inspector General, for the duration of such waiver or variance.

§16-2E-6. Inspection; inspection warrant.

 (a) The Office of Health Facility Licensure and Certification shall inspect each birthing center annually, including a review of patient records, to ensure that the facility complies with this article and the applicable rules.

(b) The Office of Health Facility Licensure and Certification shall perform unannounced complaint and verification inspections at birthing centers, including a review of patient records, to ensure that the facility complies with this article and the applicable rules.

(c) During an onsite inspection, the inspectors shall make a reasonable attempt to discuss each potential violation with the administrator or governing body of the birthing center before issuing a formal written notification.

(d) Any action taken to correct a violation shall be documented in writing by the administrator or governing body of the birthing center and may be verified by follow-up visits by the Office of Health Facility Licensure and Certification.

(e) Notwithstanding the existence or pursuit of any other remedy, the Inspector General may, in the manner provided by law, maintain an action in the name of the state for an inspection warrant against any person, partnership, association, or corporation to allow any inspection or seizure of records in order to complete any inspection allowed by this article or the rules promulgated pursuant to this article, or to meet any other purpose of this article or the rules promulgated pursuant to this article.

§16-2E-7. License limitation; denial; suspension; revocation.

(a) The director, in consultation with the Inspector General, may, by order, impose a ban on the admission of patients or reduce the patient capacity of the birthing center, or any combination thereof, when he or she finds upon inspection of the birthing center that the licensee is not providing adequate care under the birthing center's existing patient quota, and that an imposition of a ban on admissions or reduction in quota, or any combination thereof, would place the licensee in a position to render adequate care. Any notice to a licensee of a ban on new admission or reduction in quota shall include the terms of the order, the reason therefor, and the date set for compliance.

(b) The director, in consultation with the Inspector General, shall deny, suspend, or revoke a license pursuant to this article if the provisions of this article or of the rules promulgated pursuant to this article are violated. The director, in consultation with the Inspector General, may revoke a birthing center's license and prohibit all licensed disciplines associated with that birthing center from practicing at the birthing center location based upon annual, periodic, complaint, verification, or other inspection and evaluation.

(c) Notice of any such license denial, suspension, or revocation shall be by written notice given to the licensee stating the grounds for such denial, suspension, or revocation.

(d) If a license is denied or revoked as herein provided, a new application for license shall be considered by the director if, when, and after the conditions upon which the denial or revocation was based have been corrected and evidence of this fact has been furnished with the new application. A new license shall then be granted after proper inspection, if applicable, has been made and all provisions of this article and rules promulgated pursuant to this article have been satisfied.

(e) If the license of a birthing center is denied, suspended, or revoked, the owner, governing body, or administrator, or any combination thereof, shall cease to operate the center, clinic, facility, office, or program as a birthing center as of the effective date of the denial, suspension, or revocation. The owner or lessor of the birthing center property is responsible for removing all signs and symbols identifying the premises as a birthing center within 30 days of the denial, suspension, or revocation. Any administrative appeal of such denial, suspension, or revocation shall not stay the denial, suspension, or revocation.

(f) Upon the effective date of the denial, suspension, or revocation, the administrator of the birthing center shall advise the director and the Board of Pharmacy of the disposition of all medications located on the premises. The disposition is subject to the supervision and approval of the director. Medications that are purchased or held by a birthing center that is not licensed may be deemed adulterated.

(g) If the license of a birthing center is suspended or revoked, any person named in the licensing documents of the facility, including persons owning or operating the birthing center, may not, as an individual or as part of a group, apply to operate another birthing center for up to five years after the date of suspension or revocation. The director, in consultation with the Inspector General, may grant a variance pursuant to section five of this article to the prohibition of this subsection.

§16-2E-8. Violations; penalties; injunction.

(a) Any person, partnership, association, or corporation which establishes, conducts, manages, or operates a birthing center without first obtaining a license as herein provided, or who violates any provision of this article or any rule lawfully promulgated pursuant to this article, shall be assessed a civil penalty by the director, in consultation with the Inspector General, in accordance with this section. Each day of continuing violation after assessment shall be considered a separate violation.

(b) If a birthing center or any owner, governing body, or administrator is found to be in violation of any provision of this article, unless otherwise noted herein, the director, in consultation with the Inspector General, may limit, suspend, or revoke the birthing center's license.

(c) If the birthing center's administrator or governing body knowingly and intentionally misrepresents actions taken to correct a violation, the director, in consultation with the Inspector General, may impose a civil money penalty not to exceed $10,000 and, in the case of any owner-operator birthing center, limit or revoke a birthing center’s license.

(d) If any owner of a birthing center that requires a license under this article fails to apply for a new license for the birthing center upon a change of ownership and operates under new ownership, the director, in consultation with the Inspector General, may impose a civil money penalty upon the owner, not to exceed $5,000.

(e) If anyone operates, owns, or manages an unlicensed birthing center that is required to be licensed pursuant to this article; or procures or attempts to procure a license for a birthing center for any other person by making or causing to be made any false representation, the director, in consultation with the Inspector General, may assess a civil money penalty of not more than $20,000.

(f) Civil money penalties may be in addition to or in lieu of any other action that may be taken by the director, in consultation with the Inspector General, or any other board, court, or entity.

(g) In determining whether a civil money penalty is to be imposed and in fixing the amount of the penalty, the director, in consultation with the Inspector General, shall consider the following factors:

(1) The gravity of violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the birthing center's actions or the actions of any administrator, governing body, or any licensed professional, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

(2) What actions, if any, the owner or administrator took to correct the violations;

(3) Whether there were any previous violations at the birthing center; and

(4) The financial benefits that the birthing center derived from committing or continuing to commit the violations.

(h) Upon finding that a licensed professional has violated provisions of this article or rules adopted pursuant to this article, the director shall provide notice of the violation to the applicable licensing board.

§16-2E-9. Due process; injunction.

(a) Within 10 days of receipt of the notice required in section 7 or 8, or both, of this article, the birthing center may submit a request for an administrative hearing before the Board of Review or an informal meeting to address the notice and reason stated therefore.

(b) The birthing center and its owner or owners and the Office of Health Facility Licensure and Certification will be entitled to representation by legal counsel at the informal meeting and at the administrative hearing at their own expense, respectively.

(c) All of the pertinent provisions of §29A-5-1 *et seq.* of this code and 69 CSR 01 shall apply to and govern any formal hearing authorized by this article and any rules promulgated pursuant thereto.

(d) If a birthing center fails to request a hearing within the time frame specified, he or she shall be subject to the full limitation, enforcement action, or penalty, or any combination thereof, imposed pursuant to section 7 or 8, or both of this article.

(e) The filing of a request for an administrative hearing or an informal meeting does not stay or supersede the enforcement of a limitation, enforcement action, or penalty, or any combination thereof, imposed pursuant to section 7 or 8, or both of this article.

(f) Any party who is dissatisfied with the decision of the Board of Review as a result of the formal hearing provided in this section may, within 30 days after receiving the notice of the decision, petition the West Virginia Intermediate Court of Appeals, in term or in vacation, for judicial review of the decision.

(g) The court may affirm, modify, or reverse the decision of the Board of Review and either the applicant or the licensee, or the Inspector General may appeal the court's decision to the West Virginia Supreme Court of Appeals.

(h) Notwithstanding the existence or pursuit of any other remedy, the Inspector General may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association, or corporation to restrain or prevent the establishment, conduct, management, or operation of any birthing center or violation of any provision of this article or any rule lawfully promulgated thereunder without first obtaining a license in the manner herein provided.

§16-2E-10. Advertisement disclosure.

Any advertisement made by or on behalf of a birthing center though public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, social media, or through written or recorded communication shall include the name of, at a minimum, the administrator or individual from the governing body responsible for the content of the advertisement. No person, entity, or facility shall represent itself as a birthing center or use the term "birth center" or "birthing center" as its title, or part of its title, in any advertising, publications, or other forms of communication unless licensed as a birthing center in accordance with the provisions of this article and the rules promulgated pursuant to this article.

§16-2E-11. Rules; minimum standards for birthing centers.

(a) The Inspector General shall promulgate rules in accordance with the provisions of W. Va. Code §§29A-3-1, *et seq*. for the licensure of birthing centers to ensure adequate care, treatment, health, safety, welfare, and comfort of patients at birthing centers. These rules shall included, at a minimum:

(1) The process to be followed by applicants seeking a license;

(2) The qualifications and supervision of licensed and non-licensed personnel at a birthing center and training requirements for all facility health care practitioners who are not regulated by another board;

(3) The plan for collaboration with other providers, agencies, or organizations for services not directly provided by the birthing center;

(4) The management, operation, staffing, and equipping of the birthing center;

(5) The clinical, medical, patient, and business records kept by the birthing center;

(6) The procedures for inspections and for review of utilization and quality of patient care;

(7) The standards and procedures for the general operation of a birthing center, including, but not limited to, facility operations, physical operations, infection control requirements, health and safety requirements, and quality assurance;

(8) The criteria used to identify a facility as a birthing center;

(9) The standards and procedures to be followed by an administrator in providing, supervision, direction, and control of individuals employed by or associated with a birthing center;

(10) Data collection and reporting requirements;

(11) The criteria and requirements related to required services and specific functions of a birthing center;

(12) The provisions for requesting and responding to a written request for a variance or waiver;

(13) The provisions for administrative due process; suspension, revocation, or denial of a license; ban on admissions; reduction in census; and civil money penalties, and the time frames for the same;

(14) Such other standards or requirements as the Inspector General determines are appropriate.

(b) The Legislature finds that an emergency exists and, therefore, the Inspector General shall file an emergency rule to implement the provisions of this section pursuant to the provisions of §29A-3-15 of this code.

NOTE: The purpose of this bill is to modernize the birthing center statute by updating language to make the statute more consistent with nationally recognized best practices in the field and by making the administrative requirements and processes associated with birthing center licensure more streamlined and consistent with other facility types regulated by the Office of Health Facility and Certification.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.