

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES
OF THE STATE OF MONTANA

In the matter of the adoption of NEW) NOTICE OF PUBLIC HEARING ON
RULES I through XIV pertaining to) PROPOSED ADOPTION
licensure of abortion clinics)

TO: All Concerned Persons

1. On August 16, 2024, at 2:00 p.m., the Department of Public Health and Human Services will hold a public hearing via remote conferencing to consider the proposed adoption of the above-stated rules. Interested parties may access the remote conferencing platform in the following ways:

(a) Join Zoom Meeting at: <https://mt-gov.zoom.us/j/83348476453?pwd=QW00d0pkaEdObIZwbn5lelBsQ1BVUT09>, meeting ID: 833 4847 6453, and password: 490712; or

(b) Dial by telephone: +1 646 558 8656, meeting ID: 833 4847 6453, and password: 490712. Find your local number: <https://mt-gov.zoom.us/u/kdQgXwAKfg>.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on August 2, 2024, to advise us of the nature of the accommodation that you need. Please contact Bailey Yuhas, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I PURPOSE (1) The purpose of these rules is to establish the minimum licensing requirements for the licensure of abortion clinics, pursuant to Title 50, chapter 20, part 9, MCA.

(2) For purposes of this subchapter, abortion clinics include facilities described at 50-20-901, MCA.

(3) Terms used in these rules will have the definitions provided in 50-20-901, MCA.

(4) The minimum licensing requirements established by these rules are designed to encompass the requirements which an abortion clinic must meet if it performs or provides all legally permissible abortions.

(5) Certain of these requirements may be waived if not necessary in light of the scope of, and any gestational limits on, the abortions to be performed or provided by the applicant or licensed abortion clinic. The license issued by the department will identify such limitations on the scope and gestational age of abortions for which the abortion clinic is licensed, and the requirements that have

been waived as a result of such limitations. The failure to comply with such limitations will constitute a violation of the abortion clinic's license.

AUTH: 50-20-901, 50-20-903, MCA

IMP: 50-20-901, 50-20-902, 50-20-903, 50-20-904, MCA

NEW RULE II MINIMUM STANDARDS FOR ABORTION CLINICS:

LICENSING (1) A clinic or other facility that performs surgical abortions or that provides abortion-inducing drugs to five or more patients each year must be licensed as an abortion clinic.

(2) An application for licensure of an abortion clinic must be received by the department, and must include:

- (a) name of the applicant;
- (b) location of the abortion clinic;
- (c) administrator of the abortion clinic;
- (d) medical director of the abortion clinic;
- (e) qualifications of the administrator, medical director, and all professional staff;

(f) disclosures regarding:

(i) whether the applicant, owner, or affiliate has operated an abortion clinic that was closed as a direct result of issues of patient health and safety;

(ii) whether the owner or any clinic staff has been convicted of a felony offense; and

(iii) whether the owner or any clinic staff was ever employed by a facility owned or operated by the applicant that closed because of administrative or legal action;

(g) the type(s) of abortions the abortion clinic will perform or provide, and any gestational limits to such services; and

(h) an attestation that the applicant is of reputable and responsible character and is able to comply with all rules applicable to abortion clinics.

(3) An applicant must submit, with the application, administrative and legal documentation concerning information relating to (f); inspection reports, if any; and violation remediation contracts, if any.

(4) The abortion clinic will submit a license fee of \$450 to the department with the initial application, and with each annual renewal application.

(5) The department will conduct inspections of abortion clinics as follows:

(a) Abortion clinics will receive an annual licensure inspection to determine compliance with the applicable Administrative Rules of Montana and Montana Code Annotated related to licensing of abortion clinics.

(b) If the department receives a complaint relating to an abortion clinic, it will conduct an investigation which may include additional inspection of the abortion clinic if needed to resolve the complaint.

(c) Licensed premises must be open to inspection by the department or its authorized representatives, and access to all records must be granted to the department, at all reasonable times.

(6) The department may deny, suspend, or revoke the license of an abortion clinic pursuant to 50-5-207, MCA.

AUTH: 50-20-903, MCA

IMP: 50-20-902, 50-20-903, 50-20-904, MCA

NEW RULE III MINIMUM STANDARDS FOR ABORTION CLINICS:

PHYSICAL PLANT (1) An abortion clinic must be constructed and maintained so as to prevent as much as possible the entrance and harborage of insects, rodents, and other vermin capable of transmitting disease including, without limitation, rats, mice, mosquitos, and flies.

(2) Patient rooms within the abortion clinic must be, at minimum, 100 square feet.

(a) There must be 4-foot available space on 1 side of the examination table and 3-feet on all other sides.

(3) The facility must have, at minimum, 2 exits no more than 80 feet apart.

(a) All exits must have lit egress lighting paths leading to the exits.

(4) All corridors within an abortion clinic must be at minimum 6-foot in width.

(5) Locks are prohibited on all doors to which a patient may have access.

(6) Abortion clinics must comply with all local building authority requirements.

(7) Any provision of this rule may be waived at the discretion of the department if conditions in existence prior to the adoption of this rule or construction factors would make compliance extremely difficult or impossible and if the department determines that the level of safety to patients and staff is not diminished.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE IV MINIMUM STANDARDS FOR ABORTION CLINICS:

POLICIES AND PROCEDURES (1) Each abortion clinic must have a policy and procedure manual that is readily available to all facility staff, the department, and patients.

(2) A documented review/update to the policy and procedure manual must be done biennially by the facility medical director.

(3) The policy and procedure manual must include a current organizational chart.

(4) At minimum, the manual must include policies and procedures on:

(a) the different services that are offered at the clinic;

(b) maintaining and securing medical records;

(c) security for both patients and staff;

(d) obtaining consent, including:

(i) informed consent by the patient;

(ii) parental consent and/or parental notification with respect to patients under the age of 18, to the extent legally permissible; and

(iii) wait time between consent and treatment;

(e) follow-up care;

(f) initial and ongoing staff training, including:

(i) training on mandatory reporter requirements; and

(ii) law enforcement training, or if law enforcement training is not available, training acceptable to the department, on identifying and assisting women and girls who are coerced into abortion or who are victims of rape, incest, or sex trafficking;

(g) provision to patients of a hotline telephone number to assist women and girls who are coerced into abortion or who may be victims of rape, incest, or sex trafficking;

(h) staff screening and acquisition of a background check;

(i) patient/clinical files, in accordance with [NEW RULE VII(3)];

(j) emergency procedures, in accordance with [NEW RULE IX(3)];

(k) types of anesthesia to be used by the abortion clinic, the conduct of anesthesia assessments, and the criteria to be used in conducting anesthesia assessments, in accordance with [NEW RULE X(1)(b) through (d), (3), and (4)]; and

(l) infection controls, in accordance with [NEW RULE XII(2) and (3)].

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE V MINIMUM STANDARDS FOR ABORTION CLINICS:

MEDICAL DIRECTOR QUALIFICATIONS (1) An abortion clinic must have a medical director who has a current physician license in good standing with the Montana Board of Medical Examiners.

(2) The medical director must obtain 8 continuing education units (CEUs) in abortions or a related subject annually.

(3) The medical director is responsible for:

(a) overseeing treatment delivered in the facility;

(b) developing and reviewing facility policies and procedures; and

(c) overseeing the performance of the medical staff.

(4) The medical director participates in establishing competency criteria for medical personnel, including training in procedures performed at the facility.

(5) The medical director can also serve as the abortion clinic administrator.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE VI MINIMUM STANDARDS FOR ABORTION CLINICS: STAFF

FILES (1) The facility is responsible for maintaining a file on each employee. Employee files may be inspected by the department at any time. If the file is not maintained at the facility, it must be made available to the department within 24 hours of request.

(2) At a minimum, the employee file must contain:

(a) the employee's name;

(b) a job description signed by the employee;

(c) documentation of employee orientation, signed by the employee;

(d) a copy of current credentials, certification, or professional licenses required to perform the duties described in the job description;

(e) a name-based or FBI fingerprint background check; and

(f) documentation of annual training required in accordance with the policies adopted pursuant to [NEW RULE IV(4)(f)].

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE VII MINIMUM STANDARDS FOR ABORTION CLINICS:

PATIENT FILES (1) An individual clinical record must be established for each person receiving care. Each record must be accurate, legible, and promptly completed. The record must include at least the following:

- (a) patient identification including the patient's full name, sex, address, date of birth, and next of kin;
- (b) admitting diagnosis;
- (c) significant medical history and results of physical examination;
- (d) anesthesia reports;
- (e) procedure reports;
- (f) pertinent laboratory and pathology reports as indicated and tests for RH Negative factor. A pregnancy test or pathological exam of tissue shall be recorded to verify pregnancy;
- (g) nurses' notes including admission, preoperative, and recovery;
- (h) preoperative and postoperative orders;
- (i) any allergies and abnormal drug reactions;
- (j) discharge note, discharge diagnosis, and instructions given to the patient;
- (k) documentation of properly executed informed patient consent which includes notice of transfer when deemed appropriate; and
- (l) documentation:
 - (i) that the patient was provided a hotline telephone number for women who are coerced into an abortion or who are victims of rape, incest, or sex trafficking;
 - (ii) of the assistance provided to the patient if abortion clinic staff suspect the patient may be coerced into an abortion or may be the victim of rape, incest, or sex trafficking; and
 - (iii) of compliance with any applicable mandatory reporting requirements with respect to the patient.

(2) To ensure confidentiality, security, and physical safety of a patient's medical record, the abortion clinic must designate a person to oversee and manage the clinical records.

(3) The abortion clinic must have policies concerning clinical records. The policies must include:

- (a) the retention of active records;
- (b) the retirement of inactive records;
- (c) the timely entry of data in records; and
- (d) the release of information contained in records.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE VIII MINIMUM STANDARDS FOR ABORTION CLINICS:

SANITATION (1) Each abortion clinic must ensure the premises and equipment be kept clean and free of vermin capable of transmitting disease, including without limitation, rats, mice, mosquitos, and flies.

(2) An abortion clinic must provide housekeeping services on a daily basis.

(3) Garbage and waste receptacles must be collected, stored, and disposed of in a manner designed to prevent the transmission of disease. Containers must be washed and sanitized before being returned to work areas.

(4) Suitable equipment for rapid and routine sterilization must be available to ensure the operating room materials are sterile. Sterilized materials must be packaged, labeled, and stored in a manner to maintain sterility and identify sterility dates. Sterility requirements also include:

(a) processes for cleaning and sterilization of supplies and equipment complying with manufacturer's instructions and recommendations; and

(b) internal and external indicators demonstrating a high level of disinfection and sterilization.

AUTH:50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE IX MINIMUM STANDARDS FOR ABORTION CLINICS:

EMERGENCY PROCEDURES (1) Staff trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever there is a patient in the abortion clinic.

(2) The following equipment shall be available to the operating room: emergency call system; oxygen; assistance equipment, including airways and manual breathing bag; sonography; and emergency drugs and supplies specified by the medical staff.

(3) The abortion clinic must have a written transfer agreement with a hospital, critical access hospital, or rural emergency hospital, for transfer of patients experiencing a medical emergency.

(4) The abortion clinic must have policies and procedures in the event of emergency with documented staff training in:

(a) hemorrhage;

(b) perforation;

(c) respiratory distress/arrest;

(d) anaphylaxis; and

(e) emergency transfer to the facility with which the abortion clinic has a written transfer agreement.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE X MINIMUM STANDARDS FOR ABORTION CLINICS:

ANESTHESIA (1) The abortion clinic must:

(a) prohibit the use of flammable anesthesia;

- (b) have a policy which defines the types of anesthesia that will be used within the abortion clinic;
 - (c) conduct an assessment prior to the patient's admission as well as prior to surgical abortion to evaluate the risk of anesthesia and of the procedure to be performed; and
 - (d) have policies that address the pre-operative assessment, the post-anesthesia assessment, and the basis or criteria used in conducting such assessments; and
 - (e) prevent recirculation of smoke originating within the surgical suite.
- (2) Anesthesia must be administered only by a physician qualified to administer anesthetic agents or a certified registered nurse anesthetist (CRNA).
- (3) A pre-operative evaluation of the patient within 24 hours of surgical abortion shall be done by a physician to determine the risk of and anesthesia needed for the procedure.
- (4) Before discharge, each patient who received anesthesia must be evaluated by a physician or by a CRNA in accordance with applicable state health and safety laws, standards of practice, and abortion clinic policy. This post-anesthesia assessment must include evaluation of:
- (a) respiratory function, including respiratory rate, airway patency, and oxygen saturation;
 - (b) cardiovascular function, including pulse rate and blood pressure;
 - (c) mental status and level of consciousness;
 - (d) temperature;
 - (e) pain;
 - (f) nausea and vomiting; and
 - (g) postoperative hydration.

AUTH: 50-20-903, MCA
IMP: 50-20-903, MCA

NEW RULE XI MINIMUM STANDARDS FOR ABORTION CLINICS:
QUALITY ASSURANCE (1) Abortion clinics must have a quality assurance program that:

- (a) is ongoing;
- (b) is data-driven;
- (c) is broad in scope;
- (d) addresses clinical and administrative issues as well as actual patient outcomes;
- (e) has a defined set of quality improvement goals and objectives;
- (f) actively seeks patient feedback, evaluates complaints and suggestions, and works to improve patient satisfaction;
- (g) includes the active participation of the medical staff; and
- (h) respects the health care rights of all patients, including the right to privacy.

AUTH: 50-20-903, MCA
IMP: 50-20-903, MCA

NEW RULE XII MINIMUM STANDARDS FOR ABORTION CLINICS:
INFECTION PREVENTION AND CONTROL

(1) The abortion clinic must maintain an infection prevention and control program that seeks to minimize infections and communicable diseases. The abortion clinic is responsible for providing a plan of action for preventing, identifying, and managing infections and communicable diseases, and for immediately implementing corrective and preventive measures that result in improvement.

(a) The infection prevention and control program must include documentation that the abortion clinic has considered, selected, and implemented nationally recognized infection control guidelines.

(b) The infection prevention and control program is under the direction of a designated and qualified infection control officer who is a licensed health care professional and has training in infection control.

(2) The abortion clinic must have written policies that also address cleaning of patient treatment and care areas, including:

- (a) cleaning before use; and
- (b) cleaning between patients.

(3) The abortion clinic must have policies and processes in place for:

- (a) the monitoring and documentation of the cleaning, high level disinfection, and sterilization of medical equipment, accessories, instruments, and implants; and
- (b) minimizing the sources and transmission of infections, including adequate surveillance techniques.

(4) A system must exist for the proper identification, management, handling, transport, storage, and disposal of biohazardous materials and medical wastes, whether solid, liquid, or gas.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE XIII MINIMUM STANDARDS FOR ABORTION CLINICS:
SAFETY (1) The abortion clinic must designate a safety officer who is responsible for the facility's safety plan.

(2) The abortion clinic must have a safety program which addresses the organization's environment of care and safety for all patients, staff, and others. The elements of the safety program must include:

- (a) a process for identifying hazards, potential threats, near misses, and other safety concerns;
- (b) a process for reporting known adverse incidents to proper authorities;
- (c) a process for reducing and avoiding medication errors; and
- (d) prevention of falls or physical injuries involving patients, staff, and others.

(3) Products that carry an expiration date, including medications, reagents, and solutions, are monitored and disposed of accordingly.

(4) Prior to use, appropriate education is provided to intended operators of newly acquired devices or products to be used in the care of patients.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE XIV MINIMUM STANDARDS FOR ABORTION CLINICS: EMERGENCY PREPAREDNESS (1) Abortion clinics must develop a written disaster plan in conjunction with emergency services in the community.

(2) Abortion clinics must conduct a review or physical exercise of such procedures at least once a year, and prepare and retain on file, for a minimum of three years, a written report that includes:

- (a) date and time of the review or exercise;
 - (b) the names of staff involved in the review or exercise;
 - (c) the names of other health care facilities, if any, which were involved in the review or exercise;
 - (d) the names of other persons involved in the review or exercise;
 - (e) a description of all phases of the procedure and suggestions for improvement; and
 - (f) the signature of the person conducting the review or exercise.
- (3) Fire drills must be conducted twice annually no closer than four months apart.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

4. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) is proposing to adopt NEW RULES I through XIV.

The 2023 Legislature passed House Bill 937, an act requiring the licensing of abortion clinics. The bill was signed by the Governor on May 16, 2023. The department proposes to adopt NEW RULES I through XIV to establish licensing requirements for abortion clinics. To ensure the health, safety, and welfare of the patients served by these facilities, NEW RULES I through XIV provide requirements on emergency preparedness, emergency procedures, staff training, infection control, content and protection of patient and staff files, and policies to guide operations within the facility. Most of the proposed requirements for abortion clinics are based on the licensure and regulatory requirements for outpatient centers for surgical services, while some are derived from the regulatory requirements and minimum standards imposed on all health care facilities. In the department's judgment, these current regulatory requirements represent the appropriate level of regulatory requirements to impose on abortion clinics.

NEW RULE I

The department proposes to adopt this new rule to provide the purpose for the new rules, namely the licensure of abortion clinics in the state of Montana, consistent with the definitions and requirements set forth in HB 937, codified at 50-20-901 through 50-20-904, MCA. The department notes that the statutory definition of "abortion clinic" excludes hospitals and critical access hospitals. The department asks for

comments on whether, consistent with the apparent intent of the Legislature, rural emergency hospitals – a new category of hospital created by the Legislature in 2023 – should be administratively excluded from the definition of "abortion clinic."

As noted above, the department proposes licensure and regulatory requirements for abortion clinics based on outpatient centers for surgical services (also known as ambulatory surgical centers) – and based on the assumption that an abortion clinic would provide the full range of legally permissible abortions. The department recognizes that some abortion clinics may choose to provide a narrower range of abortion services. Consequently, the department proposes that it may waive certain regulatory requirements based on the scope of abortion services and any gestational limits identified in the abortion clinic's application. Under the proposed rule, the department would identify these items in the license issued to the abortion clinic. The abortion clinic would be required to comply with these limitations; failure to do so would constitute a violation of the clinic's license.

NEW RULE II

The department proposes to adopt this new rule to provide guidelines on initial and renewal licensing. NEW RULE II would implement 50-20-902, 50-20-904, and several provisions in 50-20-903, MCA.

Proposed NEW RULE II(1) is intended to follow the definition of "abortion clinic" in 50-20-901, MCA.

Proposed NEW RULE II(2) largely follows the requirements of 50-20-902(2), MCA, with slight language modifications for clarity. Because the department's licensure requirements for other health care facilities include the requirement for a medical director, the department proposes to require abortion clinics to have a medical director and to include the name of the medical director and his/her qualifications in the license application. The department also proposes to require the applicant to identify the type(s) of abortions the abortion clinic applicant will perform or provide and any gestational limitations to such services. This would permit the department to assess whether any regulatory requirements can be waived. The department would interpret the statutory requirement in 50-20-902(2)(a), MCA, and the proposed implementing regulatory provision in NEW RULE II(2)(h) as consistent with, and aligning to, the requirements imposed on health care facilities and applicants for health care facility licenses under 50-5-207, MCA. The attestation that the applicant is of reputable and responsible character (and is able to comply with all rules applicable to abortion clinics) would, thus, be that the applicant (1) is in good standing with the law and does not have any fraudulent past history (consistent with 50-2-207(1)(c), MCA), (2) has sufficient qualified staff and the financial ability to operate the facility in accordance with the law and rules or standards adopted by the department, (3) has no history or reports of cruelty or indifference affecting the welfare of patients or residents, (4) has no history or reports of misappropriation of the property or funds of a patient or resident or of conversion of a patient's or resident's property without their permission, and (5) has not violated any provision of Title 50, chapter 5, parts 1 through 3, MCA. The department anticipates that it would

not investigate an applicant's attestation unless warranted due to findings during an inspection or investigation or credible information is otherwise brought to its attention that is in conflict with the attestation.

NEW RULE II(3) and (4) would implement 50-20-902(3) and 50-20-903(2)(d)(ii), MCA, application requirements and fees, respectively.

NEW RULE II(5) would implement 50-20-903(2)(e) and 50-20-904, MCA, on abortion clinic inspections, and, consistent with ARM 37.106.310(4), health care facility licensing, permit the department to inspect the licensed premises and access its records at all reasonable times.. Finally, NEW RULE II(6) would implement the requirement of 50-20-903(2)(f), for procedures to address violations, by incorporating by reference 50-5-207, MCA.

NEW RULE III

The department proposes to adopt this new rule to provide standards in the physical plant of abortion clinics while also giving the department authority to waive certain requirements for existing structures. This new rule would implement 50-20-903(2)(b)(i) and (ix). The proposed requirements in NEW RULE III(1) would be based on ARM 37.106.321(1). The department proposes the requirements based on the 2018 edition of the American Institute for Architects (AIA) Guidelines for Design and Construction of Hospitals and Health Care Facilities. From this edition, the department referenced chapters pertaining to standards for all health care facilities, outpatient centers for surgical services, and birthing centers.

The proposed requirement in NEW RULE III(6) for compliance with local building authority requirements is drawn from ARM 37.106.508(3)(a), which requires outpatient centers for surgical services to comply with all local jurisdiction requirements, including state and local codes for construction.

NEW RULE IV

The department proposes to adopt this new rule that sets forth specific policies needed by abortion clinics for safe operational standards and file retention and protection, with a requirement for reviewing of policies and availability of policies. NEW RULE IV would implement a number of specific requirements in 50-20-903, MCA.

The proposed requirements of NEW RULE IV(1) through (3) are based on the general requirements in ARM 37.106.330(1), which require health care facilities to maintain a policy and procedure manual that is reviewed by the medical director or administrator at least annually. These proposed requirements reflect best practices for health care facilities.

The department also proposes that abortion clinics be required to adopt policies on certain specific topics in NEW RULE IV(4):

- The different services that are offered at the clinic. The abortion clinic would be required to identify in its policy and procedures manual the types of abortion services offered (and any limitations), consistent with its license, as well as any other services it offers. This proposed requirement is based on and is consistent with ARM 37.106.508(2)(c).
- Maintenance and security of patient records: This would implement 50-20-903(2)(c), MCA, and is consistent with regulatory requirements applicable to outpatient centers for surgical services. See ARM 37.106.512.
- Patient and staff security: This proposed policy requirement is consistent with requirements currently applicable to outpatient centers for surgical services. See ARM 37.106.507(1)(j).
- Obtaining consent: Informed consent is an important aspect of all medical treatment. Accordingly, the department proposes that abortion clinics have a policy and procedure on obtaining informed consent. Similarly, for minors, parental consent and/or notification are important. However, because the department recognizes that there is ongoing litigation on the constitutionality of parental notification and/or consent requirements, the department proposes to require such policies to the extent that requirements for parental notification and/or consent are legally permissible.
- Follow-up care: Follow-up care is important for patients of same-day facilities and clinics. Follow-up care consists of instructions on what to expect for the next few days to few weeks after the patient leaves the clinic, instructions for the patient on caring for themselves after they leave the clinic, and criteria for when to seek emergency medical treatment due to complications.
- Staff Training: Staff training is an important aspect of ensuring staff are and remain qualified for their positions; accordingly, the department proposes to require policies and procedures on the subject. This training would include:
 - Mandatory reporter training: Health care providers, including certain abortion clinic staff, are mandatory reporters. Consequently, the department proposes to require abortion clinics have policies on ensuring that staff are trained on any mandatory reporter obligations.
 - Training on identifying and assisting women and girls who are coerced into abortion or who are victims of rape, incest, or sex trafficking. This proposed requirement would implement, clarify, and expand on 50-20-903(2)(b)(xi), MCA. The department proposes to expand the required training to include not only sex trafficking, but also rape and incest. In case law enforcement does not provide such training, the department would require that the training be acceptable to the department. The department proposes to include girls in the provision to clarify that females of all ages may be coerced into abortion or be victims of rape, incest, or sex trafficking and that the training should reflect that.
- Provision of hotline number to patients to assist women and girls who may be coerced into abortion or who are victims of rape, incest, or sex

trafficking. This proposed required policy and procedure would implement 50-20-903(2)(b)(x), MCA, with clarifications and expansions similar to the above.

- Staff screening and background checks: This proposed requirement would implement 50-20-903(2)(b)(ii), MCA.

Finally, so that all required policies are identified in NEW RULE IV for ease of reference, the department includes cross-references to other proposed rules which contain requirements for certain, specific policies.

NEW RULE V

The department proposes to adopt this new rule that sets forth the requirement for abortion clinics to have a medical director and qualifications for the medical director to ensure services provided to patients are overseen by a physician. The department proposes this requirement pursuant to 50-20-903(2) and (2)(b)(ii), MCA. The department bases these proposed requirements on a review of requirements for medical directors or administrators of other health care facilities.

The department notes that the medical director for an abortion clinic does not need to be physically present at the abortion clinic and that a physician can act as the medical director of more than one abortion clinic or other health care facility.

NEW RULE VI

The department proposes to adopt this new rule to establish documentation needed in all employee files to ensure that staff are trained, have correct credentials, and are safe to be working in the facility. NEW RULE VI would implement 50-20-903(2)(b)(ii), MCA. These proposed requirements are based on, and consistent with, the requirements in ARM 37.106.315, minimum standards for employee files of health care facilities. In addition, to ensure that the department can easily audit compliance with staff training requirements, it proposes to require that employee files contain documentation of employee completion of annual training.

NEW RULE VII

The department proposes to adopt this new rule to establish required documentation to be completed and retained in patient files, how long patient files are to be retained, and the protection of patient files. NEW RULE VII would implement 50-20-903(2)(b)(x) and (xi) and (2)(c), MCA. The department proposes NEW RULE VII based, in part, on ARM 37.106.512, establishing requirements for clinical records to be established and maintained by outpatient centers for surgical services. In addition, the department proposes to require certain documentation be placed into the patient's records:

- Admitting diagnosis is relevant to a medical chart to know why the patient is receiving the treatment that they are.
- Reports of what procedure was conducted, how the procedure was executed, if there were complications, and what the end result was of the procedure. These reports may be important to have on record if there is a

- complication that requires someone to receive emergency medical care, or as evidence of procedural follow through if a complaint arises.
- Laboratory tests on patients receiving surgery or medications that may affect a person's hormone system is vital in ensuring accuracy of treatment, and ensuring there are not underlying conditions that may affect treatment or have additional risk factors. RH Negative Factor is recommended for gestational ages of eight weeks or more. RH incompatibility can cause problems with future pregnancies if not treated.
 - Nurses' notes covering admission, preoperative and recovery periods are important because they provide the record of discussions between patient and practitioner or nurse, nursing assessments which often include vitals and over all general health, if medications or treatments were prescribed by the practitioner were carried out and how they were tolerated, and in recovery, nurses' notes covering the nursing assessments which often include vitals, general health, and response to procedure or treatment.
 - Documentation of preoperative and postoperative instructions is important to a patient record to indicate what tasks were to be performed by nursing staff or the patient prior to receiving treatment and what medications or treatments were administered or provided after a procedure.
 - Since 50-20-903(2)(b)(x), MCA, requires that there be rules on the provision to patients of a hotline telephone number to assist women who are coerced into an abortion or who are victims of sex trafficking, the department proposes to require documentation that each patient was provided such notice be included in the patient's record.
 - Section 50-20-903(2)(b)(xi), MCA, requires annual training on identifying and assisting women who are coerced into an abortion or who are victims of sex trafficking (and the department is proposing administratively to encompass both women and girls and to encompass victims of rape and incest, as well as sex trafficking). The implication of this requirement is that abortion clinic staff are expected to do something if they identify such a woman (or girl). Accordingly, the department proposes to require documentation of any such assistance be placed into a patient's records if she is so identified.
 - Health care providers, including those employed by abortion clinics, are mandatory reporters. Consequently, the department proposes to require documentation of compliance with any mandatory reporting requirement be included in the patient's record.

NEW RULE VIII

The department proposes to adopt this new rule to ensure that abortion clinic facilities and the equipment used in them are kept clean, sterile, and in good condition. NEW RULE VIII would implement 50-20-903(2)(b)(i), MCA. The proposed requirements are taken from, and based on, existing health care facility regulatory requirements for sanitation. The department proposes NEW RULE VIII(1) based on ARM 37.106.321(1), in a rule on environmental control for health care facilities. NEW RULE VIII(2) would be based on ARM 37.106.320(2), in a rule on physical plant and equipment maintenance for health care facilities. NEW RULE

VIII(3) would be based on best infection control practices for health care facilities. Finally, the department proposes NEW RULE VIII(4) based on ARM 37.106.515(8), applicable to outpatient centers for surgical services. The proposed requirements reflect best practices for health care facilities.

NEW RULE IX

The department proposes to adopt this new rule to ensure the health, safety, and welfare of the patients receiving services by requiring training and policies for emergency health situations. NEW RULE IX would implement 50-20-903(2)(b)(iv) and (vi), MCA. The proposed requirements are taken from, and based on, best training practices for facilities that perform surgical procedures. Surgical procedures can produce immediate and life-threatening situations. It is imperative that equipment be available for emergency situations, and that staff be trained on the use of the equipment procedures of the clinic for the emergent event. The requirement for a transfer agreement is taken from ARM 37.106.506(1)(d), an Outpatient Center for Surgical Services regulation. This requirement is important to facilitate swift and immediate care by a local hospital in the event of an emergency.

NEW RULE X

The department proposes to adopt this new rule to establish requirements for the use of anesthesia for surgical abortions, who can administer anesthesia, and require post operative assessments to ensure the health, safety, and welfare of the patient. NEW RULE X would implement 50-20-903(2)(b)(v), MCA. The proposed requirements are taken from, and based on, ARM 37.106.514, which contains regulatory requirements for outpatient centers for surgical services on anesthesia risk and evaluation. They represent best practices for such health care facilities.

NEW RULE XI

The department proposes to adopt this new rule establishing a quality assurance program to determine if specific quality improvement objectives and goals are being met. NEW RULE XI would implement the requirements of 50-20-903(2)(b)(vii), MCA. The proposed requirements are taken from, and based on, ARM 37.106.508(4)(c)(i) through (viii), but would omit other requirements in that administrative rule, which establishes operational standards for, among other things, quality assurance/quality improvement programs for outpatient centers for surgical services. They reflect best practices for the development of a quality assurance/quality improvement program for health care facilities, including those that perform surgical procedures on an outpatient basis.

NEW RULE XII

The department proposes to adopt this new rule establishing infection control requirements to ensure that the facility is monitoring and attempting to minimize infections and communicable diseases. NEW RULE XII would implement 50-20-903(2)(b)(viii), MCA. The proposed requirements are taken from, and based on, ARM 37.106.513(1) through (3) and (10), which establish minimum standards for infection prevention, control, and safety for outpatient centers for surgical services.

They represent best practices on infection prevention and control for health care facilities.

NEW RULE XIII

The department proposes to adopt this new rule requiring abortion clinics to have a safety program and establish a safety officer who is responsible for facilitating the plan. NEW RULE XIII would implement 50-20-903(2)(b)(vii) and (viii), MCA. The proposed requirements are taken from, and based on, ARM 37.106.513(4), (5), (8), and (9), which establish minimum standards for outpatient centers for surgical services on infection prevention, control, and safety. They represent best practices on the subject for health care facilities and health care facilities that may perform surgical procedures on an outpatient basis.

NEW RULE XIV

The department proposes to adopt this new rule requiring abortion clinics to have emergency and disaster planning, for it to be in conjunction with other emergency services within their communities, and to require review/drills of emergency plans annually to ensure that in the event of a disaster, facility staff are aware of what to do to ensure patient and staff safety. NEW RULE XIV would implement 50-20-903(2)(b)(iv), MCA. The proposed requirements in NEW RULE XIV are taken from, and based on, ARM 37.106.322, which contains minimum standards for all health care facilities with respect to disaster planning. They represent best practices in the area of health care facility emergency and disaster planning.

Fiscal Impact

The department estimates that there are five abortion facilities in Montana that would be required to obtain a license under HB 937. Accordingly, the department estimates that the license application fee of \$450 per license application or renewal would generate \$2,250 on an annual basis. The department asks for comment on these estimates.

5. The department intends these licensure requirements to be effective upon adoption. Current facilities performing abortions will be afforded 30 days to submit an application for licensure as an abortion clinic, and the department will act on such applications within 60 days of receipt.

6. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Bailey Yuhas, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail hhsadminrules@mt.gov, and must be received no later than 5:00 p.m., August 23, 2024.

7. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

8. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Written requests may be mailed or delivered to the contact person in 6 above.

9. An electronic copy of this notice is available on the department's web site at <https://dphhs.mt.gov/LegalResources/administrativerules>, or through the Secretary of State's web site at rules.mt.gov.

10. The bill sponsor contact requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by email on September 5, 2023.

11. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Gregory Henderson
Gregory Henderson
Rule Reviewer

/s/ Charles T. Brereton
Charles T. Brereton, Director
Department of Public Health and Human
Services

Certified to the Secretary of State July 16, 2024.