

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

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

TO: All Concerned Persons

1. On July 26, 2024, the Department of Public Health and Human Services (department) published MAR Notice No. 37-1052 pertaining to the public hearing on the proposed adoption of the above-stated rules at page 1767 of the 2024 Montana Administrative Register, Issue Number 14.

2. The department has adopted the following rules as proposed: NEW RULE III (37.106.3103), NEW RULE V (37.106.3105), NEW RULE VI (37.106.3106), NEW RULE VIII (37.106.3108), NEW RULE IX (37.106.3109), NEW RULE X (37.106.3110), NEW RULE XI (37.106.3111), NEW RULE XIII (37.106.3113), and NEW RULE XIV (37.106.3114).

3. The department has adopted the following rules as proposed, but with the following changes from the original proposal, new matter underlined, deleted matter interlined:

NEW RULE I (37.106.3101) PURPOSE (1) through (5) remain as proposed.

(a) Unless otherwise provided in these rules, general requirements and provisions and requirements pertaining to the abortion services provided by the abortion clinic may not be waived.

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 (37.106.3102) MINIMUM STANDARDS FOR ABORTION CLINICS: LICENSING (1) remains as proposed.

(a) The following are not abortion clinics and are not required to be licensed as such:

(i) a hospital as defined in 50-5-101, MCA;

(ii) a critical access hospital as defined in 50-5-101, MCA;

(iii) a rural emergency hospital as defined in 50-5-101, MCA;

(iv) an outpatient center for surgical services as defined in 50-5-101, MCA;

and

(v) a facility that provides, prescribes, administers, or dispenses an abortion-inducing drug to fewer than five patients each year.

(2) through (6) remain as proposed.

AUTH: 50-20-903, MCA

IMP: 50-5-101, 50-20-902, 50-20-903, 50-20-904, MCA

NEW RULE IV (37.106.3104) MINIMUM STANDARDS FOR ABORTION CLINICS: POLICIES AND PROCEDURES (1) through (4)(j) remain as proposed.

(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 XI(1)(b) through (d), (3), and (4)]; ~~and~~

(l) infection controls, in accordance with [NEW RULE XII(2) and (3)]; ~~and~~
(m) if the clinic is licensed to perform abortions after the point when an unborn child may survive the procedure, measures to be taken to ensure that an infant that is born alive during an abortion procedure receives appropriate care, including lifesaving measures, consistent with and in compliance with the requirements of federal and state law.

AUTH: 50-20-903, MCA

IMP: 50-20-804, 50-20-903, MCA

NEW RULE VII (37.106.3107) MINIMUM STANDARDS FOR ABORTION CLINICS: PATIENT FILES (1) remains as proposed.

(a) patient identification including the patient's full name, sex, address, date of birth, and next of kin (for minor patients) or emergency contact (for adult patients);

(b) through (3) remain as proposed.

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

NEW RULE XII (37.106.3112) MINIMUM STANDARDS FOR ABORTION CLINICS: INFECTION PREVENTION AND CONTROL (1) through (3) remain as proposed.

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

AUTH: 50-20-903, MCA

IMP: 50-20-903, MCA

4. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

Comment #1: Two verbal and two written comments were received expressing support for the proposed regulations regarding continuing care of patient.

Response #1: The department thanks the commenters for the comments. The department appreciates the support for these proposed regulations.

Comment #2: One verbal and one written comment were received expressing support for the requirement to document the gestational age at the time of the abortion.

Response #2: The department thanks the commenters for their comments. The department appreciates their support for these proposed regulations.

Comment #3: An individual attending the hearing expressed the opinion that women receiving surgical abortions would find peace of mind that a facility has met basic standards for providing services.

Response #3: The department thanks the commenter for the comment. The department appreciates the commenter's support for these proposed regulations.

Comment #4: A verbal comment during the hearing was received expressing that it does not make sense that a beauty shop would be inspected and licensed but not a facility that provides abortion services. A similar written comment was received, indicating that a massage spa must be inspected and licensed so a clinic providing abortions should be, too.

Response #4: The department thanks the commenter for the input, and appreciates the commenter's support for these proposed regulations.

Comment #5: Two verbal and five written comments were received in support of the facility requirements for cleanliness, sterilization, safety and in good condition.

Response #5: The department appreciates the support for these proposed regulations, and thanks the commenters for their comments.

Comment #6: A verbal comment and a written statement were received expressing support for the proposed regulations surrounding operational standards, file retention, protection of patients, and staff policies.

Response #6: The department thanks the commenters for the comment, and appreciates their support for these proposed regulations.

Comment #7: Three people voiced their support at the hearing for the regulations surrounding staff training. One written comment was received supporting the proposed regulations requiring staff training.

Response #7: The department appreciates the commenters' support for these proposed regulations.

Comment #8: A verbal comment and two written comments were received in support of the proposed regulations regarding emergency procedures.

Response #8: The department thanks the commenters for the comments. The department appreciates their support for these proposed regulations.

Comment #9: Five verbal comments and three written comments were received expressing the opinion that the proposed regulations are basic, common sense, standard guidelines for medical facilities and/or outpatient surgical service facilities.

Response #9: The department thanks the commenters for their input. The department appreciates the commenters support for these proposed regulations.

Comment #10: A commenter at the hearing expressed the opinion that women may assume that abortion facilities are already inspected and regulated, and expressed support that now these facilities will.

Response #10: The department thanks the commenter for the comment, and appreciates the commenter's support for these proposed regulations.

Comment #11: Two verbal comments were received, expressing the opinion that these proposed regulations would help protect victims of abuse.

Response #11: The department thanks the commenters for their comments. The department appreciates their support for these proposed regulations.

Comment #12: A verbal comment and one written comment were received expressing the support of the proposed regulation requiring a physician's oversight of the facility.

Response #12: The department thanks the commenters for their comments, and appreciates their support for these proposed regulations.

Comment #13: Three written comments and one verbal comment during the hearing were received expressing the opinion that the proposed regulations do not infringe on women's rights or access to abortion.

Response #13: The department thanks the commenters for their comments. The department appreciates the support for these proposed regulations, and agrees that the regulations do not infringe on any woman's rights or access to abortion.

Comment #14: A written comment was received supporting the proposed requirements but stating that waivers should be granted to allow facilities opportunities to meet needs of communities.

Response #14: The department thanks the commenter for the comment. The department appreciates the support for these proposed regulations. Proposed NEW RULES I and III (ARM 37.106.3101 and 37.106.3103) include authorization for the department to waive certain requirements, depending on the scope of, and any gestational limits on, the abortions to be performed or provided by the applicant or

licensed abortion clinic. The department will work with an abortion clinic, as necessary and appropriate, to determine whether there are regulatory requirements that may be waived, given the abortion clinic's scope of services.

Comment #15: Three written comments were received expressing opinions that the proposed regulations are standards that promote women's health and safety.

Response #15: The department thanks the commenters for their comments. The department appreciates their support for these proposed regulations.

Comment #16: Two written comments were received expressing the opinion that there is no such thing as a risk-free procedure, so basic standards are required.

Response #16: The department thanks the commenters for the comments. The department agrees and appreciates the commenters' support for these proposed regulations.

Comment #17: Nine written comments were received expressing support for the proposed regulations, indicating that basic or uniform standards should be applied to all facilities that conduct a surgery, including abortion clinics.

Response #17: The department thanks the commenters for their comments. The department appreciates their support for these proposed regulations.

Comment #18: A written comment was received expressing support for the proposed regulations and expressing the opinion that an abortion physician should have admitting privileges to a hospital.

Response #18: The department thanks the commenter for the input. The department appreciates the support for these proposed regulations. While the department does not require, through these licensure requirements, that abortion providers have hospital admitting privileges, the department does require in NEW RULE IX (ARM 37.106.3109) that an abortion clinic have a written transfer agreement with a hospital, critical access hospital, or rural emergency hospital.

Comment #19: Three written comments were received in support for the proposed regulations, commenting that women deserve full disclosure and informed consent information.

Response #19: The department thanks the commenters for their comments. The department appreciates their support for these proposed regulations.

Comment #20: One written comment was received in support of the proposed regulations, expressing that complications and consequences from abortions impact the state's fiscal budget when forced to fund through Medicaid.

Response #20: The department thanks the commenter for the comment. The department appreciates the support for these proposed regulations, and acknowledges that it has received and paid Medicaid claims for emergency room visits where the diagnosis code was complications of abortion; Montana Medicaid may have paid other claims for services needed to address the consequences of abortion that were not so coded.

Comment #21: A written comment was received in support of the proposed regulations, indicating that while there are those who report that abortions are safe, there are no legal standards for these medical practices in abortion clinics.

Response #21: The department thanks the commenter for the comment. The department appreciates the support for these proposed regulations.

Comment #22: One written comment was received in support of the proposed regulations but requested that rural emergency hospitals be included in the exclusion portion of the definition.

Response #22: The department appreciates the commenter's support for these proposed regulations. Since the department adopted the statutory definition of "abortion clinic" in NEW RULE I (ARM 37.106.3101), the department interprets the request as a request for additional clarity as to the types of entities that are required to be licensed as an abortion clinic in NEW RULE II(1) (ARM 37.106.3102(1)). The department agrees that it would be appropriate to specify, in the regulations, the entities that are not required to be licensed as abortion clinics because they are excluded from the definition of the term. Under the Montana Code Annotated (MCA), a "rural emergency hospital" is defined as "a facility defined in 42 U.S.C. 1395x(kkk)(2) that is designated by the department as a rural emergency hospital in accordance with 50-5-234." 50-5-101(50), MCA. The U.S. Code, in turn, indicates that a "rural emergency hospital" is a "facility that as of December 27, 2020—(A) was a critical access hospital; or (B) was a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1395ww(d)(2)(D) of this title), or was a subsection (d) hospital (as so defined) with not more than 50 beds that was treated as being located in a rural area pursuant to section 1395ww(d)(8)(E) of this title," 42 U.S.C. § 1395x(kkk)(3) (cross-referenced in § 1395x(kkk)(2)), that meet certain additional requirements. See 42 U.S.C. § 1395x(kkk). Given that federal definition of rural emergency hospital and the fact that the definition of "hospital" in 50-5-101(25), MCA, does not expressly exclude rural emergency hospitals, the department believes that rural emergency hospitals are excluded from the definition of "abortion clinic" because that definition excludes hospitals and critical access hospitals.¹ The department's identification of the entities not required to register as abortion clinics aligns with this analysis.

¹ The department notes that its legislative proposal that would exclude "rural emergency hospitals" from the definition of "hospital" also contains a proposal to

Comment #23: A written comment was received in support of the proposed regulations, but suggested a modification to the waiver permissions by indicating which proposed regulations may be waived and for what types of facilities. The commenter suggests that proposed NEW RULES II, III(1) and (6), IV, V, and VI, VII, VIII(1), (3), and (4), XI, XII, XIII, and XIV be nonwaivable for any licensed abortion clinic. The commenter further suggested that proposed NEW RULES III (3) and (5), IX, and X be nonwaivable for any licensed abortion clinic that provides surgical abortions.

Response #23: The department thanks the commenter for the comment, and appreciates the support for these proposed regulations. The department seriously considered the commenter's recommendations, but found that implementing the recommendations was more complicated than the commenter suggested. For example, NEW RULE IV (ARM 37.106.3104) contains a requirement for policies and procedures on anesthesia, which arguably should be waivable if the abortion clinic does not perform or provide surgical abortion – but the commenter included the rule on the list of rules that should not be waivable for any licensed abortion clinic. However, the department agrees that it should provide additional guidance on the type of requirements that the department will not waive. The department, thus, amends the rule to provide that general provisions and provisions and requirements that pertain to the abortion services provided by the abortion clinic will not be waived. Thus, for example, the department will not consider requests to waive the requirement for policies and procedures on staff training or the licensure requirement itself because each is a general requirement that pertains to all abortion services. If, however, the abortion clinic does not provide surgical abortion, it will consider waiver of the requirement for policies and procedures on anesthesia or for maintaining pre- and post- operative notes in the patient's file. The department will follow the requirements in NEW RULE I (ARM 37.106.3101) when evaluating any request from an applicant or abortion clinic to waive any licensure requirement set forth in these rules.

Comment #24: A written comment was received in support of the proposed regulations with the suggestion that the department add in the differentiation of "medical waste" and "human fetal remains" as there are disposal differences.

Response #24: The department appreciates the support for these proposed regulations, and thanks the commenter for the comment. The department partially agrees with the commenter's suggestion. The department amends proposed NEW RULE XII(4) (ARM 37.106.3112(4)) to state, "A system must exist for the proper identification, management, handling, transport, storage, and disposal of biohazardous materials, medical wastes, and human fetal remains, whether solid, liquid, or gas." In this regard, the department notes that 75-10-1005(4)(c), MCA, provides that "[f]etal remains or recognizable body parts other than teeth must be

amend the definition of "abortion clinic" to exclude rural emergency hospitals, to maintain the current exclusion.

disposed of by incineration or interment," and thus identifies the proper mechanism for disposal of human fetal remains.

Comment #25: One written comment was received in support of the proposed regulations with the request that the department include a requirement for facilities to have a policy on born-alive abortions and that the baby must receive lifesaving measures.

Response #25: The department thanks the commenter for the comment. The department appreciates the support for these proposed regulations. The department agrees with the suggestion and amends proposed NEW RULE IV(4) (ARM 37.106.3104(4)) to require a policy on infants born-alive during or after an abortion procedure, which must include procedures to provide lifesaving measures in the event of a born-alive abortion. As the commenter points out, this is consistent with the requirements of 50-20-804, MCA.

Comment #26: One written comment was received in support of the proposed regulations indicating that inspection and oversight may reveal deficient practices that endanger patients, and that it is better to have it identified before it escalates.

Response #26: The department appreciates the commenter's support for these proposed regulations, and agrees that, as with all licensed health care facilities, licensure inspections and oversight may identify, and permit correction of, deficiencies before they lead to patient harm.

Comment #27: A written comment was received in support of the proposed regulations, specifically the requirement to screen for coercion, sex trafficking, and abuse.

Response #27: The department thanks the commenter for the comment and appreciates the support for these proposed regulations, especially with respect to coercion, sex trafficking, and abuse, given the data cited by the commenter.

Comment #28: Four verbal comments and one written comment were received in opposition to the licensing of abortion clinics. Commenters expressed that abortion clinics are already subject to government oversight and regulation in Montana.

Response #28: The department appreciates the comments, but believes that the commenters' premise is mistaken: Since abortion clinics are currently not subject to licensure, unlike most health care facilities, they have largely been unregulated and not subject to government oversight. In exercise of the state's police powers, the 2023 Montana Legislature determined that abortion clinics should be licensed and regulated, similar to other health care facilities, and passed H.B. 937 requiring the licensure of abortion clinics. Section 50-20-903, MCA requires the department to license and regulate abortion clinics.

Comment #29: Five verbal comments and 13 written comments were received in opposition to the licensing of abortion clinics, with the opinion that the regulations are presented as a targeted attack on abortion clinics. Many of the commenters expressed the attack was a political attack.

Response #29: The 2023 Montana legislative session passed H.B. 937, requiring the department to license and regulate abortion clinics. As indicated in the statement of reasonable necessity, the department developed the licensure requirements for abortion clinics based on the licensure requirements imposed on health care facilities in general and those imposed on outpatient centers for surgical services; the licensure requirements for outpatient centers for primary care were also considered. In light of the fact that most health care facilities are licensed and regulated and that the abortion clinic licensure requirements are based on existing licensure requirements, the department rejects the commenters' contentions that the abortion clinic licensure regulations are a targeted or political attack on abortion clinics.

Comment #30: Four verbal and three written comments were received in opposition to the proposed regulations, expressing that the proposed regulations are TRAP laws.

Response #30: The department appreciates the comment; however, for the reasons set forth in the response to Comment #29, the department rejects the commenters' contention that the abortion clinic licensure regulations are targeted restrictions on abortion providers.

Comment #31: Three verbal and six written comments were received in opposition to the proposed regulations, expressing that the proposed regulations have nothing to do with patient safety, medical standards, or health care.

Response #31: The department respectfully disagrees. There are real risks associated with both surgical abortion and medical/medication abortions, as the submission of at least one commenter substantiates. The abortion clinic licensure requirements are intended to address those risks and to help ensure the health, safety, and wellbeing of the patients served by these clinics. In this regard, the requirements are based on, and are similar to, the licensure requirements imposed on other Montana health care facilities, including outpatient centers for surgical services and outpatient centers for primary care. Furthermore, licensure inspections can detect issues and problems, before they adversely affect patient health and safety, and corrective action can be taken to address those issues and problems, as a commenter substantiates.

Comment #32: Seven verbal comments and eleven written comments were received in opposition to the licensure of abortion clinics and the proposed regulations, expressing that licensing and the proposed regulations would limit or ban access to abortions and force facilities to be shut down.

Response #32: The department disagrees. The department notes that the commenters do not explain how the licensure requirements would have the identified impacts, making it impossible for the department to respond. The department, however, believes that the licensure requirements will help ensure the safety, health, and wellbeing of abortion clinic patients. The department does not believe that the licensure requirements would limit (or ban) access to abortions or force facilities to be shut down. But, just as with other health care facilities, if an abortion clinic fails to comply with the licensure requirements, designed to help ensure the health, safety, and wellbeing of its patients, and fails to take corrective action when requested by the department, it should be subject to the same types of licensure action (denial, reduction to provisional, suspension, or revocation) as any other health care facility for the same type of violation.

Comment #33: One verbal comment and four written comments were received in opposition to the licensing of abortion clinics, indicating that licensing these facilities would deny compassionate, life-saving care to the women of Montana.

Response #33: The department disagrees with the commenters and notes that they do not provide an explanation of how a requirement for abortion clinic licensure would have the impact they identified. The department believes that the abortion clinic licensure regulations – which include, among other things, safety, quality assurance, and infection prevention and control requirements – mean that women who seek care at an abortion clinic can be sure of receiving safe care.

Comment #34: One verbal and five written comments were received in opposition to the proposed regulations indicating that the proposed regulations are not required of other providers and clinics and single out abortion clinics.

Response #34: All types of health care entities that the MCA defines as "health care facilities" (50-5-101, MCA) are subject to licensure and regulation by the department. The 2023 Montana Legislature passed, and Governor Gianforte signed, H.B. 937, requiring the licensure of abortion clinics and adding abortion clinics to the definition of a health care facility. The abortion clinic licensure regulations are based on, and are similar to, the licensure requirements imposed on other types of health care facilities. As such, abortion clinics are not singled out.

Comment #35: Two verbal and two written comments were received in opposition to the proposed regulations expressing the opinion that the licensing of abortion clinics and proposed regulations directly conflict with the mission of the Department of Public Health and Human Services.

Response #35: The department disagrees. The department's mission statement is "Serving Montanans in their communities to improve health, safety, well-being, and empower independence." One of the ways in which the department achieves this mission is to license and regulate health care facilities, now including abortion clinics, to ensure that Montanans receive safe, quality care.

Comment #36: Four verbal and fourteen written comments were received in opposition to the licensure of abortion clinics and the proposed regulations, requesting that the department reject the rules and licensure of abortion clinics.

Response #36: The department is required by H.B. 937 (codified at 50-20-901 through 50-20-904, MCA), passed by the legislature and signed by Governor Gianforte, to license and regulate abortion clinics. As a result, the department rejects the commenters' request that it reject issuance of the rules. There can be real risks associated with both surgical abortions and medical/medication abortions, as the submission of at least one commenter substantiates. The abortion clinic licensure requirements are intended to address those risks and help ensure the health, safety, and wellbeing of the patients served by these clinics. In this regard, the requirements are based on, and are similar to, the licensure requirements imposed on other Montana health care facilities, including outpatient centers for surgical services and outpatient centers for primary care. Furthermore, licensure inspections can detect issues and problems, before they adversely affect patient health and safety, and corrective action can be taken to address those issues and problems, as a commenter substantiates.

Comment #37: Five verbal and six written comments were received in opposition to the licensure of abortion clinics. Commenters expressed that abortion is safe and medically necessary and does not require government oversight.

Response #37: The 2023 Montana Legislature passed, and Governor Gianforte signed, H.B. 937 requiring the department to license and regulate abortion clinics. The legislature, thus, decided that abortion clinics should have state oversight, to help ensure the health, safety, and wellbeing of Montanans who seek their services. Contrary to the commenters' suggestion, there can be real risks associated with both surgical abortions and medical/medication abortions, as the submission of at least one commenter substantiates. The abortion clinic licensure requirements are intended to address those risks and help ensure the health, safety, and wellbeing of the patients served by these clinics. Governmental oversight of abortion clinics is, thus, warranted. Contrary to the commenters' suggestion, the fact that abortion may sometimes be medically necessary strengthens the need for, and the justification of, government oversight. And the requirements are based on and are similar to the licensure requirements imposed on other Montana health care facilities, including outpatient centers for surgical centers and outpatient centers for primary care.

Comment #38: Two verbal comments were received in opposition to the proposed regulations, indicating that providers have extensive training and knowledge.

Response #38: The department thanks the commenters for their comments, but notes that their comments prove too much: Many medical providers have extensive training and knowledge, but the department still licenses and regulates the facilities that employ such providers. Just as the department licenses and regulates other health care facilities, despite the training and knowledge of the individual providers

they employ, the department will license and regulate abortion clinics, pursuant to H.B. 937, codified at 50-20-901 through 50-20-904, MCA.

Comment #39: Five verbal comments and three written comments were received in opposition to the licensing of abortion clinics, indicating that doing so would infringe on an individual's right to privacy in their health care.

Response #39: The licensure of abortion clinics does not infringe on the right to privacy. The department takes seriously its obligation under state and federal law to protect the privacy and confidentiality of individually identifiable health information. It regulates other types of health care facilities and otherwise has access to a significant amount of sensitive identifiable health information and protects such information, as it will the information obtained as a result of its obligation to license and regulate abortion clinics. With respect to the Montana Constitution's right to privacy under which the Montana Supreme Court recognized a state constitutional right to pre-viability abortion, the department denies that these abortion clinic licensure requirements would infringe on such right.

Comment #40: Five verbal and seven written comments were received in opposition to the proposed regulations, expressing that the physical plant requirements of hallways and patient rooms were unnecessary.

Response #40: The proposed regulations on patient room and clinic hallway dimensions are based on the 2018 Guidelines for Design and Construction of Outpatient Facilities for outpatient surgery. The department included in the proposed regulations the allowance for waivers from these dimensional requirements for existing abortion clinics, as it is the department's understanding that existing facilities may not meet these requirements and that alteration to the facilities may not be feasible. These requirements would be enforced if a new facility were to be built.

Comment #41: One verbal and six written comments were received in opposition to the proposed regulations, expressing the opinion that the licensure of abortion clinics and the regulations go against the Montana Constitution.

Response #41: The department believes that the abortion clinic licensure requirements are consistent with the Montana Constitution. It understands that the constitutionality of the regulations will be litigated in a lawsuit pending in district court in Lewis and Clark County. The department intends for these regulatory requirements to be severable.

Comment #42: One verbal comment was received in opposition to the licensure of abortion clinics, indicating that unnecessary rules create barriers for patients with lower socioeconomic status, those of color, and those who live in rural areas.

Response #42: The department notes that the commenter failed to explain how abortion clinic licensure would have the identified impact, which limits the

department's ability to respond. The department disagrees with the commenter's implication that the abortion clinic licensure rules are unnecessary. Abortion clinics are currently unregulated. The 2023 Montana Legislature decided that abortion clinics should be licensed. It passed, and Governor Gianforte signed, H.B. 937 that requires the department to license and regulate abortion clinics. The licensure requirements are based on, and similar to, the licensure requirements applicable to other types of health care facilities, and should not create undue burden on abortion clinics. Consequently, the department does not believe that the rules create barriers to accessing needed care by the populations identified in the comment.

Comments #43: A verbal comment was received in opposition to the licensure and proposed regulations for abortion clinics indicating that research published by the National Institutes of Health studies have shown that regulations and restrictions lead to long waits, increased travel times, and unsafe or self-induced abortions.

Response #43: The department thanks the commenter for the comment, but notes that the commenter did not provide sufficient specificity with respect to the referenced research or studies to enable the department to identify and review the studies in order to be able to respond. In any event, the department does not believe that licensure requirements will lead to the referenced issues.

Comment #44: One verbal comment and five written comments were received in opposition to the proposed regulations surrounding the proposed charting and assessment requirements. The commenters indicated that these requirements would deny Montanans abortion services via telehealth, which would significantly impact rural areas.

Response #44: The department thanks the commenters for the comments, but disagrees with the commenter's conclusion that the regulations would necessarily deny Montanans abortion services through telehealth. There is no requirement in the proposed regulations, for example, that any physical examination, tests, or laboratory requirements be conducted by the abortion clinic. The department believes that such items could be conducted outside the abortion clinic, with the results sent to the abortion clinic in order to meet any regulatory requirements. As a result, and in light of the department's willingness to work with the facilities, the department does not agree with the comment that the effects of licensing abortion clinics, and the proposed regulations, would significantly impact rural communities.

Comment #45: One verbal and three written comments were received in opposition to the proposed regulation that requires a transfer agreement. The commenters indicate that no other facility has this requirement, and other health care facilities can send patients to emergency rooms without a transfer agreement.

Response #45: The department thanks the commenters for the comments, but believes they are mistaken. ARM 37.106.506(1)(d)(i), Minimum Standards for Outpatient Centers for Surgical Services, requires such outpatient centers to have a transfer agreement with a hospital for situations where it is determined that care is

required for more than 24 hours, or if the patient requires care that is beyond the capabilities of the surgery center.² There are similar transfer agreement requirements for outpatient centers for primary care birth centers. See ARM 37.106.1012(1)(c) and (d). The department requires this of abortion clinics so that their patients who experience a medical emergency can efficiently and promptly be transferred to a hospital, critical access hospital, or rural emergency hospital to receive necessary emergency services.

Comment #46: One verbal comment and two written comments were received in opposition to the proposed regulation of requiring a physician's oversight of the facility. The commenters express the opinion that this puts limitations on advanced practitioners from practicing their full scope.

Response #46: The department thanks the commenters for the comment, but disagrees. The department does not intend to put limits on, and nothing in the requirement that the medical director of an abortion clinic be a physician limits, the scope of practice of advanced practitioners, or prevents such individuals from practicing to the full scope of their professional licenses. The proposed regulations do not prohibit or limit their ability to work at an abortion clinic, or to provide abortion services. The proposed regulations require that a physician serve as the medical director of the facility, providing overarching oversight of the facility. The department notes that this requirement is not unique to abortion clinics. The licensure requirements for outpatient centers for surgical services and for outpatient centers for primary care require that a physician serve as the medical director of the center. See ARM 37.106.503(1), 37.106.1006(2), and 37.106.1008(3).

Comment #47: Three written comments were received in opposition to the proposed regulations indicating that the proposed regulations do not apply to facilities who provide miscarriage services in which the treatment is identical to that of abortions.

Response #47: The department thanks the commenters for their input, but respectfully disagrees with their conclusions. Most health care facilities, including those which provide miscarriage services, are already subject to licensure and regulation by the department. Given that the licensure requirements for abortion clinics are based on, and similar to, existing licensure requirements, such facilities are likely subject to requirements similar to the abortion clinic licensure requirements. The department acknowledges that there are some different or additional requirements on abortion clinics, in area(s) where there are qualitative differences between abortion clinics and facilities which provide, among other things, miscarriage services. For example, the legislature recognized in H.B. 937, and comments support, that women can be coerced into abortion and that victims of sex trafficking are also at risk of abortion. The department believes that this is also the

² Alternatively, an outpatient center physician who is present for all surgeries has to have admitting privileges at the receiving hospital or the receiving hospital has to have a coordinated transfer policy which includes the respective roles and responsibilities of the outpatient center upon arrival at the receiving hospital.

case for victims of rape and incest, which is borne out by comments submitted in this rulemaking. As a result, the abortion clinic licensure requirements contain specific requirements around this issue in NEW RULES IV and VII (ARM 37.106.3104 and 37.106.3107).

Comment #48: Three written comments were received in opposition to the licensure of abortion clinics, indicating that the unnecessary burdensome regulations and cost of licensure on providers would force the facilities out of business.

Response #48: The department thanks the commenters for their participation in the comment process, but notes that they provide no specific explanation of how the licensure and regulation of abortion clinics is unnecessary, burdensome, or how it would force the clinics out of business, which makes it difficult for the department to respond. The 2023 Montana Legislature passed, and Governor Gianforte signed, H.B. 937, requiring the department to license and regulate abortion clinics. For the reasons set forth elsewhere in this adoption notice, the department believes that the licensure requirements are necessary and impose the appropriate level of licensure requirements on abortion clinics.

Comment #49: Four written comments were received in opposition to the licensure of abortion clinics and the proposed regulations, indicating that no other form of health care in Montana is required to follow these unnecessary licensure requirements.

Response #49: The department thanks the commenters for their comments, but disagrees. Montana health care facilities are licensed and regulated by the department. Given that the abortion clinic licensure requirements are largely based on licensure requirements applicable to other health care facilities, it would be incorrect to say that other health care facilities are not subject to the same or similar licensure requirements. The department acknowledges that there are some licensure requirements that are unique to abortion clinics, but they are necessary in light of the services they provide. Please also see the response to Comment #47. Finally, the department denies that the licensure requirements are unnecessary for the reasons set forth throughout the proposal notice and this adoption notice, including the responses to Comments # 31 and # 36.

Comment #50: One written comment was received in opposition to the licensure of abortion clinics, indicating that licensing abortion clinics will make it harder for a rape survivor to get abortion treatment.

Response #50: The department notes that the commenter provided no specific explanation as to how licensing abortion clinic would have the stated impact, making it difficult for the department to respond. However, with the required staff training on identifying and assisting women and girls who are the victims/survivors of rape, as well as the requirement to document in the patient files the provision of hotline numbers and of the assistance provided to such women and girls, the department

believes that the licensure requirements may actually improve abortion clinics' treatment of rape survivors.

Comment #51: One written comment was received in opposition to the licensure of abortion clinics, requesting that the department not alter the rules or create any barriers to access for this legal and lifesaving health care.

Response #51: The department notes that the commenter provides no explanation as to how the licensure of abortion clinics would create the asserted barriers to care, which makes it difficult for the department to respond. The department does not believe that abortion clinic licensure would have the asserted impact on access to care. Rather, the licensure requirements would help protect the health, safety, and wellbeing of the patients who seek care from abortion clinics.

Comment #52: One written comment was received in opposition to the proposed regulations indicating that the proposed regulations are an anti-choice attempt at making rules so difficult that facilities are forced to close.

Response #52: Please see the responses to Comments #29 and #30.

Comment #53: A written comment was received in opposition to the licensure of abortion clinics, expressing the opinion that government needs to get out of health care.

Response #53: The department understands the sentiments behind the comment. However, health care is the subject of significant regulation at both the federal and state levels. And while this is the case, and the department licenses and regulates other health care facilities, it is entirely appropriate for the department to license and regulate abortion clinics – as the department was directed to do in H.B. 937. It is especially appropriate when the abortion clinic licensure requirements are based on, and similar to, the licensure requirements for other health care facilities.

Comment #54: One written comment was received in opposition to the proposed regulations. This commenter expressed that abortion clinics are outpatient facilities, and the commenter does not understand why they are not required to just follow outpatient facility requirements.

Response #54: The department thanks the commenter for the comment. H.B. 937, codified at 50-20-901 through 50-20-904, MCA, requires the department to license these facilities separately as abortion clinics. The department notes, however, that proposed regulations took into consideration, and are based on, licensure requirements applicable to outpatient centers for surgical services and outpatient centers for primary care. The department also considered the regulatory requirements generally applicable to health care facilities, as well as research into the regulatory requirements in other states.

Comment #55: Two written comments were received in opposition to the licensure of abortion clinics and the proposed regulations, indicating that the requirements will add additional burden to women's health and the underserved populations.

Response #55: The department thanks the commenters for their participation in the rulemaking process, but notes that the comments do not explain how the licensure requirements will have the asserted effect. This makes it difficult for the department to respond. However, the department believes that the licensure requirements would help protect the health, safety, and wellbeing of the patients – including women and underserved populations – who may seek care from abortion clinics.

Comment #56: A written comment was received in opposition to the licensure of abortion clinics, expressing the opinion that licensure will force facilities to close, and when there is closure of abortion clinics there is no place for women to go. The commenter expresses health care does not get better when there are fewer options.

Response #56: The department rejects the commenter's conclusion that licensure will force abortion clinics to close and the asserted result, for which the commenter provided no specific explanation, making it difficult for the department to respond.

Comment #57: One comment was received in opposition to the licensure of abortion clinics indicating that having facilities classified as an "abortion clinic" will garner social stigma, drive away patients, and cause hate-based public responses such as picketing and riots.

Response #57: The department appreciates the commenter's concern, but points out that Montana facilities that perform abortions or provide abortion services are already classified as abortion clinics, as any internet search on "Montana abortion clinics" demonstrates. The statutory requirement – implemented by these regulations – that such facilities be licensed as abortion clinics does not newly classify them as abortion clinics and, thus, does not create or increase any risk that may be associated with such classification.

Comment #58: One written comment was received in opposition of the proposed regulations indicating that rural emergency hospitals should be included in the exclusion of the definition of an abortion clinic.

Response 58: The department thanks the commenter for the input. Please see the response to Comment #22.

Comment #59: One written comment was received in opposition to the proposed regulations, indicating that the current regulations are already enough, and the facilities should be left alone.

Response #59: The department thanks the commenter for the comment, but points out that, unlike most types of health care facilities which are subject to departmental licensure and regulatory requirements, abortion clinics have been largely

unregulated. The 2023 Montana Legislature passed H.B. 937, requiring the department to license and regulate abortion clinics. The department has chosen to adopt licensure requirements that are based on the existing licensure requirements applicable to outpatient centers for surgical services, outpatient centers for primary care, and health care facilities generally.

Comment #60: One written comment was received in opposition to the licensure of abortion clinics, expressing the opinion that there is no need for governmental control or regulations of women's bodies.

Response #60: The department disagrees that the licensure and regulation of abortion clinics amount to government control or regulation of women's bodies – a contention for which the commenter provided no support.

Comment #61: One written comment was received in opposition to the licensure of abortion clinics, expressing that licensing the facilities does not protect a woman's right to choose.

Response #61: The department believes that the abortion clinic licensure regulations – which include, among other things, safety, quality assurance, and infection prevention and control requirements – mean that women can safely exercise their right to an abortion.

Comment #62: One written comment was received in opposition to the proposed regulations, expressing that practitioners are approved by the medical board, so the facilities do not need more regulations.

Response #62: The department thanks the commenter for the comment, but disagrees. There is a difference between the licensure of medical practitioners and the licensure of health care facilities. The 2023 Montana Legislature passed H.B. 937, requiring the department to license and regulate abortion clinics. The medical board licenses individual medical practitioners, which does not meet the intent of the licensure of the abortion clinics. The comment also ignores the fact that many health care facilities that are licensed and regulated by the department employ medical practitioners who are approved (or licensed) by the medical board – but there is no suggestion that such regulations are unnecessary.

Comment #63: Three written comments were received in opposition to the proposed regulations, expressing that if the regulations were really health care-focused, they would pertain to all clinics, not just abortion clinics.

Response #63: The department rejects the commenters' suggestion that the abortion clinic licensure regulations are not really health care-focused. As explained in detail in the statement of reasonable necessity, the proposed requirements are based upon – and sometimes taken, verbatim (or virtually verbatim) from – licensure requirements for outpatient centers for surgical services and/or general requirements for health care facilities; some are also based on requirements for outpatient centers

for primary care. That the entities providing abortion services are referred to as "clinics," instead of "facilities" or "outpatient centers," does not mean that they should not be held to similar licensure standards. Please see also the responses to Comments #29 and #30.

Comment #64: A written comment was received in opposition to the proposed regulations, expressing the opinion that they would increase administration costs, allow for citations, and force expensive burdens on providers and patients.

Response #64: The department acknowledges that the licensure requirements may impose certain burdens on abortion clinics. Those burdens, however, are similar to the burdens imposed on other types of health care facilities by the applicable licensure requirements and are neither undue nor unnecessary. And the 2023 Montana Legislature decided, in passing H.B. 937, that abortion clinics should be licensed and regulated by the department just as other health care facilities are.

Comment #65: Two comments were received in opposition to the proposed regulations. The commenters point out that "anesthesia" and "patient rooms" are not defined which would result in facilities having to play a guessing game of how to be compliant.

Response #65: The department disagrees and rejects the commenters' implication. It is not necessary for the department to define every term used in its regulations, especially when the terms, such as "anesthesia" are medical terms that have well accepted medical meanings. The department also believes that a "patient room" is clearly understood to be a room in which a patient is assessed or treated.

Comment #66: Two comments were received in opposition to the proposed regulations, indicating that while the regulations indicate the ability for a waiver, they do not explain what a provider would have to demonstrate to be eligible for a waiver.

Response #66: The department disagrees that the proposed regulations do not explain what an abortion provider would have to demonstrate to obtain a waiver. The department indicated in the proposed rules that it may waive certain regulatory requirements based on the scope of abortion services and any gestational limits identified in the abortion clinic's licensure application. The department's intent is to allow the department to work one-on-one with abortion clinics to determine what requirements can be waived based on the proposed scope of abortion services and gestational limits. The issuance and identification of any waivers in the license would occur after review of the application, in discussion with the provider, and be individualized. The most obvious example is that, with respect to an abortion clinic whose application indicated that it would not be providing surgical abortions, but only medication abortions (such as through the use of mifepristone and misoprostol), the department – after review of the application and discussion with the applicant – may waive regulatory requirements associated exclusively with surgical abortion in the issued license.

Comment #67: One comment was received in opposition to the licensure of abortion clinics and the proposed regulations, expressing that addition of regulations is not proven to improve patient outcomes.

Response #67: The department disagrees: Just as with other health care facility licensure regimes, abortion clinic licensure requirements ensure that a licensed abortion clinic meets certain minimum standards that help ensure the health, safety, and welfare of the patients served by these clinics. That understanding informed the Montana Legislature's decision to pass, and Governor Gianforte's decision to sign, H.B. 937. That legislative enactment requires the department to license and regulate abortion clinics.

Comment #68: One comment was received in opposition to the licensure of abortion clinics and the proposed regulations, indicating that requiring all abortion clinics to have standards of those that do surgical abortions, or of outpatient centers for surgical services, is a misunderstanding of what abortion clinics do.

Response #68: The comment displays a misunderstanding of the proposed regulations. While the department's approach in the proposed regulations assumed that an abortion clinic would provide the full range of legally permissible abortions, the department recognized that some abortion clinics may choose to provide a narrower range of abortion services – and proposed that the department may waive certain regulatory requirements based on the scope of abortion services and any gestational limits identified in the abortion clinic's license application. The intent is to allow the department to work one-on-one with abortion clinics to determine what requirements can be waived based on the proposed scope of abortion services and any gestational limits.

Comment #69: One written comment was received in opposition to the licensure of abortion clinics and the proposed regulations, indicating that the licensure and regulations will put essential health care out of reach.

Response #69: The department disagrees that the licensure of abortion clinics and the proposed regulations would put essential health care out of reach. The department's approach to abortion clinic licensure and regulation aligns with its approach to licensure and regulation of all health care facilities. The regulations are necessary to implement H.B. 937, enacted in 2023, that requires the department to license and regulate abortion clinics.

Comment #70: One written comment was received in opposition to the licensure of abortion clinics, expressing the opinion that by doing so, it will cause harm to those of color, indigenous people, those that live in rural areas, LGBTQ+ individuals, and the disabled.

Response #70: The department disagrees that the licensure of abortion clinics would cause harm to the populations identified by the commenter, for which the commenter provided no evidence or explanation. The department believes that

these regulations are necessary to ensure the health, safety, and welfare of the patients served by abortion clinics. They are necessary to implement H.B. 937, enacted in 2023, that requires the department to license and regulate abortion clinics.

Comment #71: One written comment was received in opposition to the proposed regulation involving Rh testing, indicating this is not needed for early abortions as the percentage is very low that the Rh factor causes complications or risks in early abortions.

Response #71: The department thanks the commenter for the comment, but does not agree. Rh testing is typically done at a first prenatal visit to scan for a potential risk of Rh incompatibility, so that the appropriate treatment can be provided. Rh incompatibility occurs when a woman with Rh-negative blood is pregnant with a fetus with Rh-positive blood. In such circumstances, mixing of the mother's and fetus's blood can result in the development of Rh antibodies in the mother. These antibodies can cross the placenta and attack the fetus's red blood cells, causing hemolysis; importantly, this can cause problems in later pregnancies in which the fetus is Rh-positive. The test identifies whether there is a potential for a risk if the blood is mixed during a delivery or an abortion, and therefore, for the safety of future pregnancies. This test report would be important to have on record if complications were indicated during an abortion.

Comment #72: A written comment was received in opposition to the proposed regulations, expressing that telemedicine will be eradicated with the proposed regulations, which will deny access to rural communities.

Response #72: The department thanks the commenter for the comment, but disagrees with the commenter's conclusion that the regulations would eradicate telemedicine. There is no requirement in the proposed regulations, for example, that any physical examination, tests, or laboratory requirements be conducted by the abortion clinic. The department believes that such requirements could be met outside the abortion clinic, with the results sent to the abortion clinic in order to meet any regulatory requirements. As a result, and in light of the department's willingness to work with the facilities, the department does not agree with the comment that the effects of licensing and regulating abortion clinics would infringe on health care access for rural communities.

Comment #73: A written comment was received pertaining to NEW RULE II. The commenter indicates that the justification for the requirements in NEW RULE II(2)(f)(ii), which state, "whether the owner or any clinic staff has been convicted of a felony offense," is not included in the statement of reasonable necessity. The commenter asks why the department is adopting statutory language into rule language here and in other areas of the proposed regulations.

Response #73: The department appreciates the comment. The department reiterated certain statutory requirements in the proposed regulation regarding the

requirements for the license application, so that all the applicable requirements are in one location. The department disagrees that the justification for the NEW RULE II(2)(f)(ii) (ARM 37.106.3102(2)(f)(ii)) requirements is not in the statement of reasonable necessity: The reasonable necessity is that the statute requires the application to include such disclosure, and the statement of reasonable necessity states that "[p]roposed NEW RULE II(2) largely follows the requirements of 50-20-902(2), MCA."

Comment #74: A written comment was received regarding NEW RULE IV(2). The commenter indicates the proposed regulation requires biennial review of the policy and procedure manual, but the statement of reasonable necessity indicates annual review.

Response #74: The department thanks the commenter for bringing the discrepancy to its attention. The proposed regulation contains the correct requirement.

Comment #75: A written comment was received regarding NEW RULE IV(3)(d)(iii). The commenter suggests this be removed as there is no justification as to the reason to have a wait time between signing the consent and the abortion initiation.

Response #75: The department thanks the commenter for the comment, but declines to make the change suggested by the comment. This allowance of time between consent and initiating the abortion allows for staff to screen for coercion, sex trafficking, rape, or incest, and allows time for women who may be feeling coerced to change their mind or confirm their desire to proceed with the treatment. The department does not require a specific duration, but expects abortion clinics to provide sufficient time for the referenced screening.

Comment #76: A written comment was received regarding NEW RULE VII(1)(a). The commenter does not believe next of kin should be required for individuals of adult age.

Response #76: The department thanks the commenter for the comment. The department does not agree with the suggestion to modify the proposed NEW RULE VII(1)(a) (ARM 37.106.3107(1)(a)) to include only minors. With any procedure, there are identified, and unidentified, risks. In the event that a complication or life-threatening situation arises, it is imperative that the abortion clinic is able to contact someone close to the patient. However, in light of the comment, the department will modify the provision, with respect to adult patients, to a requirement for an emergency contact.

Comment #77: A written comment was received regarding NEW RULE XI(1)(a) through (c). The commenter asks how the department intends to enforce the regulations and suggests the department remove them or describe the expectations.

Response #77: The department thanks the commenter for the comment. The department has not yet developed survey tools and interpretive guides for the

inspection and surveying of abortion clinics. The department will address the criteria to meet the requirements of the rules at that time. The department notes, however, that NEW RULE XI (ARM 37.106.3111), and the provisions referenced by the commenter, are identical to requirements for a quality improvement/quality assurance program for outpatient centers for surgical services in ARM 37.106.508(2)(c), which contains three additional requirements not in NEW RULE XI. The department intends for its approach on NEW RULE XI (ARM 37.106.3111) to be consistent with its approach to the identical requirements applicable to such outpatient centers.

Comment #78: A written comment was received regarding NEW RULE VI. The commenter asks how employees' personal identifying information is protected by the department, and what clinic employee information is subject to Montana's sunshine law. The commenter adds that the department should be required to contact the employee prior to requesting to look at the employee's information.

Response #78: The department thanks the commenter for the comment. Case law on Montana's public records act recognizes the need to balance transparency and the right to know against issues of personal privacy. When the department inspects employee files, it would be looking to determine whether the requirements set forth in proposed NEW RULE VI (ARM 37.106.3106) are met. Consistent with current practice, if deficiencies are found in relation to staff files, identities are withheld from the public report, with staff being identified as "Staff #1," "Staff #2," etc. The department reviews staff files at all licensed health care facilities, and does not notify the employee prior to the review of the employee file. Accordingly, the department declines to include a requirement that an employee be contacted before department staff review the employee's file.

Comment #79: A written comment was received with the opinion that the proposed requirements for employee records for abortion clinic staff are more specific than for other medical facilities' employee records. The commenter recommends making employee record requirements the same for all medical facilities.

Response #79: The department thanks the commenter for the comment, but does not agree with the suggestion. The department licenses health care facilities that offer a wide range of services, and that have a wide range of positions and professionals that work in the facilities. Requirements surrounding staffing requirements, and the requirements of staff files, are specific to the type of facility and the services provided. In this case, the requirements for abortion clinic employee files are largely the same as the requirements that generally apply to health care facilities. *Compare* NEW RULE VI (ARM 37.106.3106) *with* ARM 37.106.315. The department adds documentation of annual training, to facilitate audit of employee training; documentation of annual training in employee files is also a common practice. Background checks are also a common requirement and best practice in the health care field; the results of such checks are usually maintained in the employee's files.

Comment #80: A written comment was received with the opinion that the proposed requirement for patient files should meet the requirement standards in ARM 37.106.402(4).

Response #80: The department disagrees. ARM 37.106.402(4) permits hospital medical records to be abridged to a set of core medical records beginning ten years after the patient's death or discharge (or, for minors, ten years after the date the patient attains the age of majority or dies, if earlier); the provision identifies the minimum information that such abridged core medical records should contain. Even if the department agreed that the standard for hospital medical records should apply to abortion clinics, it would not be appropriate to apply the standard in ARM 37.106.402(4) to records concerning current patients.

Comment #81: A written comment was received, expressing the opinion that the department is proposing too prescriptive and onerous rules on abortion clinics. The commenter agrees to the protection of patients and ensuring they receive safe, effective treatment, but expresses the opinion that the proposed requirements are not needed to meet that goal and are excessive.

Response #81: The department disagrees that the licensure requirements are too prescriptive and onerous, or that they are not needed for the protection of patients and ensuring safe effective treatment or are excessive. They meet the specific licensure requirements of 50-20-902 and 50-20-903, MCA, and are based on the existing licensure requirements for outpatient centers for surgical services, outpatient centers for primary care, and/or for health care facilities, generally. And, as previously noted, the department may waive certain regulatory requirements based on the scope of abortion services and any gestational limits identified in the abortion clinic's application and subsequent license. Thus, the department believes that the licensure requirements represent an appropriate level of regulatory requirements to impose on abortion clinics.

Comment #82: A written comment was received expressing the opinion that the fiscal impact analysis was too narrow in only looking at the annual licensing fee. The commenter expresses that the department did not take into consideration the requirement to have certain room sizes, implementation of the infection control plan, development of safety and disaster plans. Additionally, the requirement to have a physician as a medical director will require additional costs on the facilities. The commenter requests the fiscal analysis be redone with attention to the costs associated with getting into compliance with proposed regulations.

Response #82: The department believes that the commenter may have misunderstood the purpose of the fiscal impact statement. In contrast to an economic impact statement (see 2-4-405, MCA), a fiscal impact statement examines the impact of the rulemaking on the state budget: i.e., payments made by and/or received by the department. The analysis of the fiscal impact does take into consideration all of the proposed regulations. Under 2-4-405, MCA, the department is required to prepare an economic impact statement upon written request of the

Children, Family, Health and Human Services Interim Committee based on a majority vote; no such request has been made by that committee. Accordingly, the department does not agree that the fiscal impact should be reevaluated or revised.

Comment #83: A written comment was received with the opinion that when considering the effects of the proposed rules, it is anticipated that the impact costs will be higher, which should trigger the rule package to be republished for public comment.

Response #83: Please see the response to Comment #82.

Comment #84: A written comment was received regarding the first paragraph of the statement of reasonable necessity. The commenter notes that the statement of reasonable necessity indicates that the abortion clinic rules are based on outpatient centers for surgical services, but if 70% of abortions are done using medication, which is not a surgical procedure, what is the rationale for basing the entire chapter off the outpatient center for surgical services. The commenter asks if facilities that do not provide surgical abortions would be exempt from NEW RULE IX(2).

Response #84: The department appreciates the opportunity provided by the comment to reiterate what it said in the statement of reasonable necessity concerning the basis for the abortion clinic licensure requirements and how the department intends to implement them. When writing the proposed regulations, the department referenced rule requirements for outpatient centers for surgical services, as well as for outpatient centers for primary care and health care facilities generally, and researched requirements for similar clinics around the country. As the department noted in the statement of reasonable necessity for NEW RULE I, "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 recognize 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." The department anticipates that if an abortion clinic does not perform or provide surgical abortions and does not have an operating room, the department would waive licensure requirements in NEW RULE IX(2) (ARM 37.106.3109(2)), applicable to surgical abortions, which require operating rooms.

Comment #85: A written comment was received regarding the statement of reasonable necessity for NEW RULE I, expressing the opinion that the exclusion of hospitals from the definition of an abortion clinic is contradictory with the intent of "ensure the health, safety, and welfare of the patients."

Response #85: In the statement of reasonable necessity for NEW RULE I, the department noted the exclusion of hospitals from the definition of abortion clinic

because the definition of "abortion clinic" contained in H.B. 937, and codified at 50-20-901(1), MCA, excluded hospitals from the definition of an abortion clinic. Furthermore, the department rejects the idea that the exclusion is contrary to the department's purpose to "ensure the health, safety, and welfare of the patients": Hospitals are already subject to an array of licensure requirements that are designed to ensure the health, safety, and welfare of hospital patients. See ARM 37.106.401 (incorporating by reference Medicare conditions of participation). In light of those requirements, it would be redundant to impose abortion clinic licensure requirements on hospitals.

Comment #86: A written comment was received expressing that NEW RULE VIII is unclear. The commenter indicates it is unclear if the sterilization is in reference to equipment, or full sterilization of the room like an operating room.

Response #86: The department does not believe that NEW RULE VIII(4) (ARM 37.106.3108(4)), to which the comment relates, is unclear. That rule speaks of "ensuring the operating room materials are sterile," of "sterile materials," "processes for cleaning and sterilization of supplies and equipment," and "safe processing of items undergoing high level disinfection and sterilization." Moreover, the provision is taken virtually verbatim from existing ARM 37.106.515(8), applicable to outpatient centers for surgical services, and the department intends to interpret and implement it consistent with its interpretation and implementation of that rule provision.

Comment #87: A written comment was received regarding NEW RULE VII, expressing the opinion that it does not meet best practice standards to require clinics to document inapplicable information.

Response #87: The department thanks the commenter for the comment. As the department noted in the statement of reasonable necessity and elsewhere in this adoption notice, the licensure requirements are based on the assumption that an abortion clinic would provide the full range of legally permissible abortions, and that the department may waive requirements that are not applicable to the type of abortions provided by any particular abortion clinic. As such, the department clarifies, again, that it is not its intent to require abortion clinics to document information that would not be applicable with respect to the scope of abortion services provided by the abortion clinic.

5. The department intends these licensure requirements to be effective upon adoption. Subject to the stipulation in *Planned Parenthood et al. v. State of Montana et al.*, Cause No. ADV 2023-592 (1st Jud. Dist.) and any subsequent order of the court, 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.

/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 September 10, 2024