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

In the matter of the amendment of ARM 37.106.301, 37.106.310, and 37.106.330 pertaining to Health Care Facility Standards	))))	NOTICE OF AMENDMENT

TO: All Concerned Persons

1. On July 26, 2024, the Department of Public Health and Human Services published MAR Notice No. 37-1094 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 1830 of the 2024 Montana Administrative Register, Issue Number 14.

2. The department has amended the following rules as proposed: ARM 37.106.301, 37.106.310, and 37.106.330.

3. 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: A written comment was received in support of the proposed amendments. The commenter suggests two modifications to the proposed amendments. The first suggestion is to include direction on how patients are to be informed of any specific interventions or services that are not offered and be referred to a practitioner or facility that will provide the services that the practitioner or facility does not provide. The second suggestion is to clarify what "need to know" means in ARM 37.106.330(2)(e). The commenter expresses the opinion that it would be important for others providing direct care and those who do scheduling be informed of the individuals opting to not participate in a procedure or service.

RESPONSE #1: The department appreciates the commenter's support for the proposed amendments, but does not agree with the proposed modifications. The department's purpose and responsibility in amending the licensure rules based on H.B. 303 is to ensure that health care facilities have in place policies for allowing medical practitioners within a health care facility the opportunity to opt out of providing services based on conscience. The first suggestion is beyond the scope of this rulemaking, but the department notes that, consistent with the confidentiality policies required in ARM 37.106.330(2)(e), health care facilities are free to adopt policies and procedures on how patients are informed on the availability of services. The department believes that such confidentiality/need to know requirement should be implemented in the same way as health care facilities use and protect other confidential information in an employee's personnel file.

COMMENT #2: One verbal comment was received in opposition to the proposed amendments. The commenter expresses the opinion that the proposed amendments are unnecessary as there are already federal regulations in place regarding safeguarding the rights of conscience. The commenter indicates that the proposed amendments add red tape to state government. The commenter indicates these requirements are dangerous for people in rural areas and will create unnecessary burdens.

RESPONSE #2: The department acknowledges that there are federal regulations on conscience that implement federal statutes on the protection of conscience rights. However, the authority to enforce those federal protections is limited to the federal government. The Montana Legislature chose to pass, and Governor Gianforte to sign, H.B. 303, to protect the conscience rights of Montana health care institutions and medical practitioners. Consistent with its statutory authority to license and regulate health care facilities, the department adopts these rules to enable it to implement and enforce the protections in H.B. 303. The department rejects the idea that the requirements are dangerous for people in rural areas or that they create unnecessary burdens.

COMMENT #3: One verbal comment was received in opposition to the proposed amendments, expressing that the proposed amendments reflect an extreme religious or conscience clause which will allow health care providers to discriminate against their patients without consequence. The commenter expresses the opinion that these proposed amendments clearly ignore public health.

RESPONSE #3: The department appreciates the concern behind the comment, but rejects the idea that the rules or H.B. 303, which they implement, reflects an extreme religious or conscience clause, and notes that there are similar protections for health care providers in federal law. *See, e.g.,* Church Amendments, 42, U.S.C. § 300a-7 (enacted in the 1970s); the Coats-Snowe Amendment, 42 U.S.C. § 238n; (enacted in 1996); the Weldon Amendment *in* Further Consolidated Appropriations Act, 2024, Pub. L. 118-47, Division D, § 506(d) (enacted annually as part of the federal Labor HHS appropriations act). The department also rejects the idea that the rules ignore public health, a claim for which the commenter provided no specific support or explanation.

COMMENT #4: One verbal comment was received in opposition to the proposed amendments, expressing the opinion that the rights of any health care provider to exert their conscience must be balanced with the right of the patient and their ability to receive care without delay or harm. The commenter expresses that the amendments allow for the denial of care without liability and without protection of the patient.

RESPONSE #4: The department appreciates the concern behind the comment; however, the department notes that, in H.B. 303, the Montana Legislature chose to require health care institutions/facilities to respect the conscience rights of the medical practitioners, while also noting that such requirements may not be construed

to affect the obligation of health care institutions (i.e., hospitals) to provide emergency medical treatment as set forth in 42 U.S.C. § 1395dd (EMTALA). For discussion of EMTALA with respect to H.B. 303 conscience rights, see response to Comment #11.

COMMENT #5: A verbal comment was received in opposition to the proposed amendments, indicating that the proposed amendments require health care facilities to develop policies and procedures consistent with the statute, but does not require the development of polices to ensure quality of care. The commenter also indicates that the proposed amendments do not include the provision in Montana Code Annotated that states, "nothing in this section may be construed to relieve a healthcare institution of the requirement to provide emergency medical treatment to all patients."

RESPONSE #5: The department thanks the commenter for the comment, but notes that measures relating to quality of care are beyond the scope of this rulemaking, which is to adopt measures, within the department's authority, to implement H.B. 303. The department notes, however, that various health care facilities, including hospitals, critical access hospitals, rural emergency hospitals, outpatient centers for surgical services, and outpatient centers for primary care are subject to federal and/or state requirements involving quality of care and quality assurance measures, and that the licensure rules for abortion clinics, finalized elsewhere in this edition of the Montana Administrative Register, include quality assurance program requirements. The same is true for the emergency medical stabilization and treatment requirements in 42 U.S.C. § 1395dd.

COMMENT #6: A written comment was received regarding the proposed amendments to ARM 37.106.310, indicating that the commenter does not approve of the department's proposal to use the term "health care facility" instead of the term used in H.B. 303, "health care institution," and recommends using the term in the statute.

RESPONSE #6: The department declines to make the recommended change. As the department noted in the statement of reasonable necessity, the department does not have regulatory authority over all of the types of medical institutions included in H.B. 303's definition of "health care institution," but that the types of medical institutions identified in that definition with respect to which the department does have authority to license and regulate align with the statutory (and regulatory) definition of "health care facility." Accordingly, the department maintains the use of that term in these rules. The department, moreover, is concerned that the use of the term "health care institution" would introduce confusion over the scope of the department's regulatory authority with respect to medical institutions.

COMMENT #7: A written comment was received in opposition to the proposed amendments to ARM 37.106.310 [sic], expressing a concern that members of a health care team will not want to complete portions of their job description based on their conscious [sic] and this could cause additional challenges in finding team

members to complete the needed/required work, especially in critical access hospitals that have limited number of staff already.

RESPONSE #7: The department assumes that the commenter had meant to refer to the proposed amendment of ARM 37.106.330; ARM 37.106.310, which the commenter references, establishes that *the department* will not discriminate against health care facilities for the exercise of their conscience rights. On the substance of the comment, the department notes that H.B. 303 requires health care institutions, including health care facilities, to respect the conscience rights of the medical practitioners associated with their facilities. The requirements in these rules are merely mechanisms to ensure compliance with H.B. 303. Accordingly, the department declines to make any changes to the rules in response to this comment.

COMMENT #8: A written comment was received in opposition to the proposed amendments to ARM 37.106.330, arguing that many hospitals already have policies and procedures in place that meet the intent of H.B. 303, that the requirements in the amendment go beyond what is required in H.B. 303, and that health care institutions are required by state and federal laws to meet staff training requirements, suggesting that the training requirement is an undue burden on a highly regulated industry.

RESPONSE #8: The department disagrees. The department decided to establish the requirement for such policies and procedures and compliance with such policies and procedures as a licensure requirement, so that there is a departmental enforcement mechanism if a health care facility fails to comply with the H.B. 303 conscience protections. If the commenter is correct that many hospitals/health care providers already have policies and procedures in place to meet the intent of H.B. 303, then these regulatory requirements should not impose an undue burden on them because most come straight from H.B. 303. And given that there are pre-existing staff training requirements, adding another module, on conscience protections and how to exercise them should not impose an undue burden on health care facilities/institutions. The reports the department received concerning how some Montana health care facilities handled requests for religious exemption from the U.S. Centers for Medicare & Medicaid Services COVID-19 vaccine mandate suggest that there may be a need for such an enforcement mechanism as well as an all-staff training requirement so that medical practitioners know their conscience rights and facility management know the facility's legal obligations with respect to medical practitioners' conscience claims. Finally, the requirement to maintain the confidentiality of information concerning the exercise of conscience, to be disclosed only as needed, is consistent with the confidentiality required of much personnel information.

COMMENT #9: A written comment, from a commenter that opposed H.B. 303, expressed that if the department determines that the amendments to ARM 37.106.330 are necessary, it should require that a team member wanting to exercise conscience as a basis for not participating in a health care service must make the request in writing and the request be signed by the practitioner objecting. The

commenter indicates this is expressed in H.B. 303, and should be included in the minimum requirements if the department moves forward with keeping the amendments to ARM 37.106.330.

RESPONSE #9: The department declines to make the suggested revision. Section 50-4-1103(2), MCA states in part, "A health care institution may require the exercise of conscience as a basis for not participating in a health care service to be made in writing and signed by the medical practitioner objecting." The law indicates a health care institution "may" require a written and signed conscience claim, leaving it up to the discretion of such organizations. Consistent with H.B. 303, the department intends to continue to leave this decision up to the health care facility.

COMMENT #10: A written comment on the proposed amendments to ARM 37.106.330(3) requested a definition of "abortion," suggesting that the requirement only apply to elective abortion.

RESPONSE #10: The department thanks the commenter for the input, but declines to make the suggested revision. The provision implements 50-20-111(2) and 50-4-1103(4), MCA, which cross-references 50-20-111, MCA. For purposes of 50-20-111, MCA, the Montana Code Annotated provides a definition of "abortion" in 50-20-104, MCA. Given the context, the department believes that this definition is equally applicable to 50-4-1103(4), MCA. As a result, the department cannot agree that the intent of the statute was to limit these H.B. 303 protections to the elective abortion context.

COMMENT #11: A written comment inquired as to how these regulations would impact a facility's ability to meet the Emergency Medical Treatment and Labor Act (EMTALA).

RESPONSE #11: While the commenter raised the question in the context of a comment on abortion (*see* Comment #10), there is no suggestion in the comment as to how the conscience protections of H.B. 303, implemented and furthered by these rules, would conflict with a hospital's requirements to provide care and meet its EMTALA obligations. With respect to hospitals participating in the federal Medicare program, EMTALA imposes certain obligations with respect to patients experiencing an "emergency medical condition." In the abortion context, the department notes that the EMTALA definition of "emergency medical condition" includes conditions that "could reasonably be expected to result in (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy," *see* 42 U.S.C. § 1395dd(e)(1)(A)(i), indicating that EMTALA is designed to protect both pregnant women and their unborn children. Furthermore, there are several federal statutes that provide significant conscience protections for health care providers, especially with respect to abortion. These include the Church Amendments, 42 U.S.C. § 300a-7, the Coats-Snowe Amendment, 42 U.S.C. § 238n; and the Weldon Amendment to the annual Labor HHS appropriations act, *see, e.g.,* Further Consolidated Appropriations Act, 2024, Pub. L. 118-47, Division D, § 506(d). While the federal government issued guidance on EMTALA and abortion, it

conceded, before the U.S. Supreme Court, that federal conscience protections, for both hospitals and individual health care providers, apply in the EMTALA context (and that EMTALA does not override either set of conscience protections). *See Moyle v. United States*, 603 U.S. __, 144 S. Ct. 2015, 2021. (Barrett, concurring) (citation to transcript of oral argument). Whether EMTALA ever requires abortion appears to remain an open question. *See id.,* 144 S. Ct. at 2021 n.1 (federal government concession that EMTALA requires abortion only in an emergency acute medical situation where the woman's health is in jeopardy if she does not receive an abortion then and there); *Moyle*, 603 U.S. __, 144 S. Ct. 2015, 2027 (Alito, joined by Thomas and Gorsuch, dissenting) ("This case presents an important and unsettled question of federal statutory law: whether [EMTALA] sometimes demands that hospitals perform abortions and thereby preemts Idaho's recently adopted Defense of Life Act . . . "); *Texas v. Becerra*, 89 F.4th 529 (5th Cir. 2024) (affirming district court injunction of enforcement of CMS guidance that EMTALA requires physicians to provide abortion when necessary stabilizing treatment for emergency medical condition and preempts contrary state law). Accordingly, the department does not believe that the requirements of H.B. 303 and the department's implementing regulations would implicate hospitals' EMTALA obligations.

COMMENT #12: A written comment was received in opposition to the proposed amendments, expressing concern that there is no requirement in rule to inform patients attempting to receive health care services why care is being denied to them.

RESPONSE #12: Please see the response to Comment #1.

/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