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

In the matter of the amendment of)	NOTICE OF AMENDMENT
ARM 37.82.102 and 37.86.104)	
pertaining to Medicaid coverage of)	
abortion services)	

TO: All Concerned Persons

- 1. On December 23, 2022, the Department of Public Health and Human Services published MAR Notice No. 37-1024 pertaining to the public hearing on the proposed amendment of the above-stated rules at page 2353 of the 2022 Montana Administrative Register, Issue Number 24.
 - 2. The department has amended the above-stated rules as proposed.
- 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:

<u>COMMENT #1</u>: Several commenters expressed privacy concerns with the proposed rules and that a woman's right to privacy is specifically protected under the Montana Constitution. Several commenters suggested the proposed rule is an attempt to not comply with the Montana State Constitution and the Supreme Court decision: Armstrong vs. State.

RESPONSE #1: The department disagrees with these comments. The Montana Supreme Court in *Armstrong v. State*,1999 MT 261, 296 Mont. 361, 989 P.2d 364 (Mont. 1999), interpreted the provision in the Montana Constitution recognizing a fundamental right to individual privacy as including a right to personal autonomy over the decision whether to keep or terminate a pregnancy prior to viability. The department does not challenge that conclusion of the Montana Supreme Court in this rulemaking.

This rulemaking addresses only the question of when the Montana Medicaid program will pay for abortion services. Pursuant to the statutes governing the program, the Montana Medicaid program is only authorized to pay for medically necessary services for Medicaid beneficiaries. This rulemaking defines medical necessity for abortion purposes so that the definition cannot be used to authorize payment of elective nontherapeutic abortions, requires the submission of documentation to support the medical necessity of the abortion, and imposes prior authorization/prepayment review, to ensure that the Medicaid program is only paying for abortion services where that statutory limitation is met.

In *Jeannette R. v. Ellery,* 1995 Mont. Dist. LEXIS 795 (1st Jud. Dist., May 22, 1995), the district court found that the Montana statutory requirement to pay for medically necessary health care services meant that the Medicaid program is required to pay

for abortions that are medically necessary, but the court emphasized that its decision "does not conclude that the state of Montana must fund elective, nontherapeutic abortions" and, in fact, stated ""[i]t is clear that the state need not fund nontherapeutic elective abortion"). Jeanette R., 1995 Mont. Dist. LEXIS 795, *26, *29; see also ld. at *4 ("this case has nothing to do with indigent women who may seek an elective abortion. In other words, this case has nothing to do with abortions that are not medically necessary, as that determination is made by a physician.").1 The requirements established in this rulemaking are imposed to ensure that the Montana Medicaid program only pays for services for which there is statutory authority to cover – and that it does not pay for elective, nontherapeutic abortions. While the Montana Supreme Court grounded the right to abortion that it recognized in 1999 in Armstrong in the Montana Constitution, it also looked to the caselaw of the U.S. Supreme Court and the lower federal courts that, prior to *Dobbs v. Jackson* Women's Health Organization, 142 S. Ct. 2228 (2022), recognized a privacy right in the U.S. Constitution encompassing a right to obtain an abortion. In Beal v. Doe, the U.S. Supreme Court held that "the provisions of the Social Security Act do not require a State, as a condition of participation, to include the funding of elective abortions in the Medicaid program." Beal v. Doe, 432 U.S. 438, 447 n.15 (1977).2 In Maher v. Roe, the U.S. Supreme Court upheld a Connecticut regulation that required prior authorization for state Medicaid benefits for medically necessary first-trimester abortions and submission of, among other things, the attending physician's certification that the abortion is medically necessary. The U.S. Supreme Court noted that "[t]he decision whether to expend state funds on nontherapeutic abortion is fraught with judgments of policy and value over which opinions are sharply divided. Indeed, when an issue involves policy choices as sensitive as those implicated by public funding of nontherapeutic abortions, the appropriate forum for their resolution in a democracy is the legislature." Maher v. Roe, 432 U.S. 464, 479 (1977). The Supreme Court also held that "[i]t is not unreasonable for a State to insist upon a prior showing of medical necessity to insure that its money is being spent only for authorized purposes." Id. at 480. That is the department's goal in this rulemaking.

<u>COMMENT #2</u>: Several commenters expressed opposition to the proposed rules and suggest health care provider records already sufficiently document when and why abortions are medically necessary, as they do for all other services.

¹ The prior authorization/prepayment review of the medical documentation submitted to the Montana Medicaid program to support the medical necessity of the abortion services will be conducted by medical professionals.

² A later decision of the U.S. Supreme Court upheld the constitutionality of the Hyde Amendment, the annual appropriations rider that restricts the use of federal funds to pay for abortions provided through the Medicaid program, finding that it did not violate the Due Process or Equal Protection guarantees of the Fifth Amendment or the Establishment Clause of the First Amendment – and that states participating in the Medicaid program had the right to fund only those medically necessary abortions for which they received federal reimbursement. *See, e.g., Harris v. McRae*, 448 U.S. 297 (1980).

RESPONSE #2: The department acknowledges the commenters' contention that health care provider records sufficiently document when and why abortions are medically necessary. However, none of that documentation is currently submitted to the Medicaid program, so that the program may ensure that it only pays for medically necessary abortion services. If, as the commenters suggest, health care provider records already document the medical necessity of such abortions, the requirement to submit such documentation (and other, routinely kept medical records) should impose little burden on such abortion providers. The Montana Medicaid program proposed to institute consistent documentation requirements. This decision was made following the in-depth review of abortion claims paid by Montana Medicaid, as directed by the 2021 Montana legislature. The review concluded that when additional documentation was submitted it often lacked sufficient diagnosis or other information to support medical necessity. Instead, the claims typically correlated to an assessment of the situation, rather than documentation to support the medical necessity. With respect to the need for documentation to support medical necessity, please also see the proposal notice.

<u>COMMENT #3</u>: A commenter expressed opposition to the proposed amendment and suggests existing provisions of the Hyde Amendment already limit access to abortions, and the proposed restrictions would create unnecessary administrative hurdles, increase costs, and deny coverage for medically necessary health care.

RESPONSE #3: It is the department's responsibility to ensure compliance with federal and state laws. The Hyde Amendment limits when federal funds can be utilized for abortion services. As interpreted by the *Jeannette R.* district court, state Medicaid statutes require the department to pay for medically necessary abortion services, regardless of whether such abortions meet the requirements of the Hyde Amendment for federal funding – but do not require the department to pay for elective, nontherapeutic abortions. The provisions proposed in MAR Notice No. 37-1024 that the department finalizes here serve to ensure Montana adheres to such statutory restrictions.

<u>COMMENT #4</u>: Several commenters expressed opposition to the proposed rules and suggest the requirement of a physical exam to determine medical necessity goes against FDA guidelines and clinical best practices which allow telehealth services for the provision of medication abortion.

RESPONSE #4: The department acknowledges that the FDA requirements and guidelines with respect to medication/chemical abortion have recently changed and permit the provision of medication/chemical abortion through telehealth services. The department also recognizes that such requirements and guidelines are being actively litigated. The department's proposal to require documentation of a physical examination and imaging will ensure that the safety and well-being of the female patient – as a Medicaid beneficiary – has been considered. For example, physical examination and imaging are especially important when medication/chemical abortions are being performed, among other things, to ensure the gestational age is

within FDA guidelines on the safety and efficacy of medication/chemical abortions, to rule out ectopic pregnancy, and to screen for potential Rh incompatibility.³

<u>COMMENT #5</u>: Several commenters expressed concerns that the proposed rules would limit the abortions that qualify for medical necessity and adding a prior-authorization review could leave many Medicaid enrollees without the care they need. The commenters also expressed concern that prolonging a pregnancy before an abortion is accessible can have negative impacts: abortion services can be more expensive, more invasive for a patient, or require a longer recovery.

RESPONSE #5: The department has a responsibility to ensure that the Montana Medicaid program only provides reimbursement for health care services for which there is statutory authority – i.e., where such services are medically necessary. The regulatory changes being made in this rulemaking – revising the definition of medical necessity for abortion services, requiring submission of documentation to establish medical necessity, and imposing a prior authorization/prepayment review requirement – are designed to ensure that the Medicaid program does not pay for abortions that are not actually medically necessary, but are, in fact, elective, nontherapeutic abortions.

With respect to the commenters' concern that prior authorization could prolong a pregnancy, which could have negative impacts, the department notes that if prior authorization is not obtained – due to an emergency situation or otherwise – the claim will not be automatically denied, but will be subject to prepayment review of the required documentation to ensure medical necessity. Separate from reimbursement, nothing in the proposed rule would expressly prohibit an authorized Medicaid provider operating within their scope of practice from performing an abortion during an emergency situation or otherwise. In addition, the department's contract with the Medicaid utilization review contractor requires completion of the prior authorization or prepayment review within three working days, considering the submission of timely and accurate documentation. Thus, the requirement for prior authorization should add only minimal time to the process.

³ The department notes that there are nonfrivolous safety concerns about the FDA's recent changes to certain risk evaluation and mitigation strategies (REMS) imposed on mifepristone and the process by which they were changed. As of the date on which this adoption notice is certified to the Secretary of State, the U.S. Court of Appeals for the Fifth Circuit has refused FDA's request to stay that part of a federal district court decision which preliminarily enjoined/stayed the effective date of FDA's changes to certain REMS in 2016 and 2021/2023, including (1) increase in the maximum gestational age for use from 49 days to 70 day; (2) reduction in required in-person office visits from three to one; (3) authorization for nondoctors to prescribe and administer mifepristone; (4) elimination of reporting of non-fatal adverse events; and (5) removal of the in-person dispensing requirement. See Alliance for Hippocratic Medicine et al. v. Food & Drug Administration et al., 2023 U.S. App. LEXIS 8815 (5th Cir. Apr. 12, 2023). The U.S. Supreme Court has administratively stayed the district court's order.

<u>COMMENT #6</u>: Several commenters expressed opposition to the proposed rules and suggest it is inconsistent with the state's duty to provide safe, legal health care to Montanans. They state the amendments to these rules are unnecessary and harmful.

RESPONSE #6: The department disagrees with the characterization of the state's duty with respect to the Medicaid program: The obligation of the Medicaid program is to pay for statutorily authorized, medically necessary health care for Medicaid beneficiaries. The rule amendments are necessary to ensure that the abortion services for which claims are submitted to the Medicaid program are medically necessary and, thus, that the department only pays for abortion services for which there is statutory authorization.

<u>COMMENT #7</u>: Several commenters expressed opposition to the proposed rules and suggest it unfairly targets lower-income residents who rely on government-provided health insurance by increasing barriers to accessing care.

RESPONSE #7: The department disagrees that the rules unfairly target lower-income residents. Consistent with the purpose of the Medicaid program and the statutory limits on Medicaid coverage of health care services, the purpose of the rules is to ensure that covered abortion services are medically necessary and that the appropriate funds are utilized to pay for them. The department notes that the documentation requirements for prior authorization/prepayment review are borne by the health care providers/facilities providing abortion services for which Medicaid reimbursement is sought, not the Medicaid beneficiaries.

<u>COMMENT #8</u>: Several commenters expressed opposition to the proposed rules and state it has been proven that limiting abortion access does not decrease the total number of abortions, but rather decreases the number of safe abortions, and increases the number of unsafe abortions.

RESPONSE #8: The department disagrees that the rules would have any direct impact on access to abortion. The rules do not prohibit any woman from obtaining an abortion or any health care provider from performing any abortion; they simply identify the requirements that must be met for abortion services to be covered by Medicaid, consistent with the statutory limitations on the program. The department has a strong obligation to ensure that such statutory limitations are being recognized in its administration of the Medicaid program.

<u>COMMENT #9</u>: Several commenters expressed opposition to the proposed rules and stated it should be up to the individuals seeking the abortion to decide if an abortion is right for them, no matter their income level. Commenters expressed that the proposed amendments are intrusive and put bureaucracy in the middle of decisions best left to doctors and patients.

RESPONSE #9: The department denies that the rules would have the impact the commenters suggest. Nothing in the rules preclude individuals from choosing an

abortion. The rules simply address when Medicaid coverage will be available for abortion services provided to Medicaid beneficiaries. Please also see the response to Comment #8.

<u>COMMENT #10</u>: A commenter expressed opposition to the proposed amendment and suggests leading organizations such as the American College of Obstetricians and Gynecologists, the American Medical Association, and the American Academy of Family Physicians strongly oppose efforts to impede access to abortion care or interfere in the relationship between a person and health care provider.

RESPONSE #10: The purpose of the rule amendments is not to impede access to abortion services or to interfere in the relationship between a person and a health care provider, and the department denies that they would unduly impact access to such services or interfere with such relationships. Consistent with law, the rule amendments simply address when Medicaid coverage will be available for abortion services provided to Medicaid beneficiaries. Please also see the response to Comment #8.

<u>COMMENT #11</u>: A commenter expressed opposition to the proposed amendment and suggests the proposed amendment would increase burdens on health care providers, limit the number and types of providers available, and restrict medication abortion, a safe and effective option for ending a pregnancy.

RESPONSE #11: The department is responsible for implementing and operating the Medicaid program in faithfulness to the scope and limitations of the Medicaid program as established by the legislature. This responsibility undergirds these rules. The department recognizes that the rules impose specific documentation requirements to establish the medical necessity of Medicaid-covered abortions and that this may have the effect of putting additional burden on some health care providers. However, the collection of much of the required information is simply good clinical practice and/or information already required to be reported, such as to the department's Office of Vital Records, or otherwise.

As noted in the proposal notice, the Medicaid program can – and does – limit Medicaid payment to services provided by certain types of health care providers, in order to comply with federal and state statutes, to protect the integrity of the Medicaid program, and to protect the health and safety of Medicaid beneficiaries. With respect to medication/chemical abortion, the department agrees that it can be a safe and effective option for ending a pregnancy if the pregnant woman has been screened and meets the requirements for a medication/chemical abortion, if there are no contraindications, if the pregnant woman has been adequately educated on medication/chemical abortion, if there is adequate monitoring, oversight, and follow up, etc. See also the response to Comment #4.

<u>COMMENT #12</u>: A commenter expressed opposition to the proposed amendment and quoted, "Abortion is an essential and time-sensitive health care procedure that 1 in 4 people will have before they turn 45 years old." (Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014," by Rachel

Jones and Jenna Jerman, is currently available online and will appear in a forthcoming issue of the American Journal of Public Health). The commenter stated without question, abortion can be medically necessary and health care providers should be able to determine the appropriate care their patients need without the department imposing limitations. By narrowing the abortions that are covered for Medicaid enrollees and requiring prior authorization, the department would be delaying and denying Montanans from getting the abortion care they need which can lead to long-lasting negative outcomes.

RESPONSE #12: The department does not deny that abortion services can be medically necessary – and, to the extent required by the Medicaid statutes and consistent with any statutory limitations imposed on the Medicaid program, will cover such abortion services. The requirements imposed by these rules are designed to ensure that the Medicaid program only pays for abortion services that are medically necessary and that, consistent with the statutory limitations on the program, it does not pay for elective, nontherapeutic abortions.

<u>COMMENT #13</u>: A commenter expressed opposition to the proposed amendment and quoted "Turnaway Study," Bixby Center for Global Reproductive Health, available at

https://www.ansirh.org/sites/default/files/publications/files/turnaway_study_brief_web .pdf, further stating studies show that a person who is denied a wanted abortion is more likely to experience life-threatening maternal and infant health complications, more likely to have a household income below the poverty line and experience economic hardship, and more likely to stay in contact with violent partners, putting them and their children at greater risk than if they were able to receive the abortion.

<u>RESPONSE #13</u>: The department acknowledges the Turnaway Study, as well as the methodological criticisms that have been leveled against it (including selection bias, poor participation rate and high attrition).

As noted in response to other comments, the purpose of the rules is to ensure that the department operates the Medicaid program consistent with the statutory limitations on Medicaid coverage of abortion services.

<u>COMMENT #14</u>: A commenter expressed opposition to the proposed amendment saying the state of Montana should ensure the provision of quality health care – including abortion – to all who need it, not only those who have private insurance or who are able to pay for care. The commenter suggests that this amendment, in contrast, will create significant, totally unnecessary physical, emotional, and financial hardship and harm for Montana Medicaid beneficiaries who require abortions.

<u>RESPONSE #14</u>: The department rejects the contention that the rules will create physical, emotional, or financial hardship or harm for Medicaid beneficiaries who need abortions. Consistent with the law, the Montana Medicaid program will continue to cover medically necessary abortions, while imposing certain conditions on Medicaid's payment for abortion services to ensure that integrity and that it is not paying for elective, nontherapeutic abortion services.

<u>COMMENT #15</u>: A commenter expressed opposition to the proposed amendment stating any policies that limit a person's choice to terminate a pregnancy, except for the last three months, consistent with the United States Constitution interpretations, in the words of two of the Justices of the Supreme Court (during their confirmation hearings) "is settled law."

RESPONSE #15: The department acknowledges that the Montana Supreme Court has interpreted the Montana constitutional right to individual privacy as including a right to personal autonomy over the decision whether to keep or terminate a pregnancy prior to viability; similarly, prior to Dobbs v. Jackson Women's Health Organization, 142 S. Ct. 2228 (2022), the U.S. Supreme Court had recognized a federal constitutional right to privacy that encompassed a right to obtain an abortion. Such constitutional right to obtain an abortion is separate and distinct from whether public funds must pay for such abortions under Medicaid for eligible beneficiaries. Both Montana and federal courts have recognized that there is no requirement that Medicaid pay for elective, nontherapeutic abortions. See, e.g., Jeannette R v. Ellery. 1995 Mont. Dist. LEXIS 795, *4, *26, *29 (1st Jud. Dist., May 22, 1995) (decision "does not conclude that the state of Montana must fund elective, nontherapeutic abortions"; "[i]t is clear that the state need not fund nontherapeutic elective abortion"; "this case has nothing to do with indigent women who may seek an elective abortion"); Maher v. Roe, 432 U.S. 464, 479-480 (1977) (upholding, against constitutional challenge, Connecticut Medicaid regulation requiring prior authorization for medically necessary first-trimester abortions and submission of attending physician's certification of medically necessity, noting "[i]t is not unreasonable for a State to insist upon a prior showing of medical necessity to insure that its money is being spent only for authorized purposes"). Here, the department's rule amendments do not serve to limit a person's exercise of her constitutional rights, but merely provide greater specificity as to when and under what conditions Medicaid will pay for abortion services for Medicaid beneficiaries.

<u>COMMENT #16</u>: The department received a comment expressing opposition to the proposed rule and stating the department should advocate for the freedom of the individual and ensure the separation of Church and State.

<u>RESPONSE #16</u>: The department rejects the implication that the rules, which address when the Montana Medicaid program will pay for abortion services provided to Medicaid beneficiaries, implicate individual freedom or the Religion Clauses of the Montana or U.S. Constitution.

The department notes that its responsibilities are established by statute. While its mission is to improve and protect the health, well-being, and self-reliance of all Montanans, that mission has to be accomplished consistent with the statutory authority provided by the legislature and with its constitutional and statutory obligations with respect to religious freedom.

<u>COMMENT #17</u>: The department received several comments opposing the amendment. The commenters stated the cost of childbirth and the cost of caring for

a child have a larger financial impact on social welfare programs than the cost of an abortion.

RESPONSE #17: The department acknowledges the comment. However, the purpose of the rules is not to save the State of Montana money, but to ensure that the Medicaid program is carried out consistent with the directives of the legislature, which limit Medicaid payment to medically necessary health care services. Since the rules do not preclude any pregnant beneficiary from obtaining an abortion – but only address when Medicaid will pay for it – and the pregnant beneficiary remains free to obtain an abortion even if Medicaid does not pay for it, the department does not know whether or how implementation of the rules will affect Medicaid childbirth costs or the cost of social welfare programs.

<u>COMMENT #18</u>: Several commenters expressed opposition to the proposed amendment and suggest the current administration has pledged "financial relief" and cutting red tape "to get rid of unnecessary government regulations" and yet, that is all this proposal does. The commenters further suggest that this amendment is contrary to the administration's goal of cutting red tape and reducing government, as well as a politically motivated mandate that focuses on punitive measures and lacks insight as to the results, rather than meeting the mission of DPHHS.

RESPONSE #18: The department rejects the notion that these rules are inconsistent with the administration's regulatory reform initiatives or the department's mission statement. As the commenter notes, the purpose of the regulatory reform initiative is "to get rid of unnecessary government regulations" and/or regulations that are unduly burdensome. Here, the department has determined that the rules are necessary to ensure compliance by providers and facilities that provide abortion services with the Medicaid purpose and limit of providing medically necessary care. As stated in the proposal notice, the results of the in-depth review of Medicaidreimbursed abortion claims – which found a consistent lack of documentation. coupled with the types of conditions routinely provided on the MA-037 forms as the basis for medical necessity – have caused the department grave concern and led it to reasonably believe that the Medicaid program is paying for abortions that are not actually medically necessary, but are, in fact, elective, nontherapeutic abortions. In such a situation, it is appropriate and consistent with the administration's commitment to the rule of law and program integrity on behalf of Montana taxpayers to impose certain new regulatory requirements to ensure compliance with the statutory limitations on the Medicaid program.

With respect to the department's mission statement, please see the response to Comment #16.

<u>COMMENT #19</u>: Several comments were submitted expressing opposition to the proposed changes and suggesting the prior authorization requirement could prohibit a woman from obtaining an abortion in an emergency.

<u>RESPONSE #19</u>: The department understands the commenters' concerns that there are instances where obtaining prior authorization is not possible. The

department proposed rules and these final rules do not require immediate rejection of claims for reimbursement for abortion services if prior authorization was not obtained. Rather, the rules provide that if prior authorization is not obtained, due to an emergency situation or otherwise, the provider's claim for payment will undergo a post-service, prepayment review. Separate from reimbursement, nothing in the proposed rule would expressly prohibit an authorized Medicaid provider operating within their scope of practice from performing an abortion during an emergency situation or otherwise.

<u>COMMENT #20</u>: A commenter expressed opposition to the proposed amendment and suggests it would only allow reimbursement from physicians and undermines the professional license and scope of practice of advanced practice nurses and PAs.

RESPONSE #20: The department disagrees that the rules undermine the professional license and scope of practice of advanced practice nurses and physician assistants. It noted in the proposal notice the ongoing litigation on whether medical practitioners other than physicians may lawfully perform abortions in the State of Montana. That is a different issue than whether the abortion is covered and eligible for payment under the Montana Medicaid program. The rules do not preclude advanced practice nurses and physician assistants from performing abortions if they are otherwise legally entitled to do so. The rule amendments only address abortion coverage and payment policies under the Montana Medicaid program and do not extend beyond that. DPHHS asserts its right to make such coverage and payment policy determinations under the Medicaid program. Federal regulations prohibit the use of federal funds for abortion services unless a physician certifies in writing, in their professional opinion, the life of the mother would be endangered if the pregnancy were carried to term, or that the abortion is necessary as a result of rape or incest. 42 C.F.R. § 441.201 defines a physician as a doctor of medicine or osteopathy who is licensed to practice in the state. To comply with federal and state statutes, to protect the integrity of the Medicaid program, and to protect the health and safety of Medicaid beneficiaries, the Medicaid program can limit Medicaid payment to services provided by certain types of health care providers, and has done so here.

<u>COMMENT #21</u>: Several commenters expressed opposition to the proposed amendment and stated Montana voters, in rejecting the recent LR-131 referendum, have made clear that Montanans do not support efforts to restrict abortion-related health services. The commenters stated the proposed amendment goes against the will of Montana voters. The commenters expressed a perception that the proposed rule amendment is a way of ignoring the voice of the voters.

RESPONSE #21: Several commenters did not address the proposed rule and instead provided comments in opposition to LR-131, or contended that the proposed rule is a way to circumvent the voters' rejection of LR-131 and enact it through administrative rule. The department disagrees. The rules address when and under what conditions the Montana Medicaid program will pay for abortion services provided to Medicaid beneficiaries. It has nothing to do with the subject of the

referendum, medical services required to be provided to infants born alive after an abortion or otherwise. Furthermore, the department has complied with all of the requirements established by the Montana Administrative Procedure Act for a rulemaking.

COMMENT #22: The department received a comment stating they felt DPHHS thought the amendment would go unnoticed by many Montanans because it is not a bill. The commenter stated it was a sneaky way of denying women health care when time is of the essence.

RESPONSE #22: The department disagrees with the commenter. First, the rules do not deny women health care; the Montana Medicaid program will continue providing coverage of medically necessary abortion services for eligible beneficiaries, with the requirement that the Medicaid provider submit, to the Medicaid program, documentation to support the medical necessity of the services. If time is of the essence for the abortion services (because of an emergency situation or otherwise), Medicaid will not deny the claim because of failure to obtain prior authorization. Rather, the provider can submit the documentation for post-service, prepayment review.

Second, there was sufficient public notice about the proposed rule to provide adequate opportunity for public participation in the rulemaking process. The department testified about the Montana Medicaid program's coverage of abortion services and the lack of supporting documentation during at least one interim committee meeting and indicated that it was considering options to address the issue. Consistent with the Montana Administrative Procedure Act, notice of the proposed amendments to the Medicaid abortion coverage rules (and of the public hearing on the proposed amendments) was published in the Montana Administrative Register and was posted to both the Secretary of State's and the department's website. Copies of the proposal notice were sent to all parties on the department's interested parties list. The proposal notice was covered by various media outlets – and the commenter clearly received notice of the proposed rule amendments. The department held a hearing on the proposed rules, attended by approximately 90 people and at which 30 individuals provided comment, and the department received 474 written submissions on the proposed rule.

<u>COMMENT #23</u>: A commenter expressed opposition to the proposed amendment and suggests there is no reason anyone should ever need to justify wanting to end an unwanted pregnancy. The only reason anyone should ever have a child is that they want to. Removing abortion care from Medicaid will lead to innumerable coercive, traumatic, and dangerous unwanted pregnancies.

RESPONSE #23: The department agrees that, ideally, all children should be loved and wanted. The department has not proposed to remove and is not removing abortion services from coverage under the Montana Medicaid program; and it will continue to cover medically necessary abortion services. The rule amendments provide greater specificity as to when Montana Medicaid funds can be utilized to pay

for abortion services and the documentation that providers will be required to furnish in order to receive Medicaid reimbursement.

<u>COMMENT #24</u>: Several comments were received in opposition stating the department should not be involved in any personal, private medical situations in any way, shape, or form.

RESPONSE #24: To the extent that the comments contend that the department should not be able to receive any personal medical information to support/document medical necessity, the department disagrees. The department is responsible for administering the Montana Medicaid program in accordance with the statutory limitation that Medicaid provide coverage only for medically necessary services. Medical records are necessary to ensure compliance with such limitation, especially when, as here, there may be questions as to whether the service is medically necessary or not. The department takes its obligation to protect this health information seriously. The information itself is protected from improper access, use, and disclosure under the HIPAA Privacy Rule, 45 CFR Parts 160 and 164 Subparts A and E, and Montana's Government Health Care Information Act, Title 50, chapter 16, part 6, MCA. The medical records and other documentation will be reviewed by medical professionals employed by the Montana Medicaid program's utilization review contractor, which is also subject to the requirements (and penalties) of the HIPAA Privacy Rule and the Montana Government Health Care Information Act. The department reminds the commenters that the Montana Medicaid program requires prior authorization for other procedures when medical necessity is in doubt, as well as conducts routine utilization reviews. These customary activities require the handling of sensitive medical records and other documentation.

<u>COMMENT #25</u>: A commenter expressed opposition to the proposed amendment and suggested it would force women to forgo abortions or have them much later in pregnancy, after waiting for paperwork to be approved, if at all, and could result in death.

RESPONSE #25: The department disagrees that the requirement for prior authorization would force women to forgo medically necessary abortions or would expose them to increased risk because of delay. The prior authorization process should not lead to delays in medically necessary care. Pursuant to its contract obligations to the department and the Montana Medicaid program, the department's utilization review vendor must complete requests for prior authorization within three working days considering the submission of timely and accurate documentation. Moreover, as discussed in response to other comments, if prior authorization cannot be obtained, due to an emergency situation or otherwise, the rules provide for post-service, prepayment review of the medical necessity documentation.

<u>COMMENT #26</u>: A commenter expressed opposition to the proposed amendment and stated the requirements interfere with or restrict a provider's ability to provide quality care to all of their patients. This commenter expressed that these restrictions could result in providers leaving the state or choosing to not practice within Montana.

<u>RESPONSE #26</u>: The department disagrees that the rules would restrict a provider's ability to provide quality care to all their patients.

<u>COMMENT #27</u>: The department received a comment in support of the proposed amendment and stated they do not support utilizing taxpayer dollars to pay for abortions.

<u>RESPONSE #27</u>: The department appreciates the support. The purpose of the rule amendments is to ensure that taxpayer funds are only used for medically necessary abortions, consistent with the statutes governing the Medicaid program.

<u>COMMENT #28</u>: A commenter expressed opposition to the proposed amendment. The commenter stated the proposed amendment assumes that some abortions are "medically necessary" while others are "nontherapeutic" or "elective." Abortion is medically necessary, just as all obstetric care and miscarriage care are medically necessary, and there is no reason to single abortion care out from other pregnancy care.

RESPONSE #28: The department disagrees with the commenter's contention that all abortions are medically necessary. The Montana legislature established the Montana Medicaid program "for the purpose of providing necessary medical services to eligible persons who have need for medical assistance." 53-6-101, MCA. As the department has recognized, there are certain medical procedures that, depending on the patient's situation in context, could have a therapeutic purpose or a nontherapeutic purpose. Thus, for example, physician services for conditions or ailments that are generally considered cosmetic in nature are not a benefit of the Medicaid program, unless, through a prior authorization process, it can be demonstrated that the physical and psycho-social wellbeing of the recipient is severely affected in a detrimental manner by the condition or ailment and certain other prior authorization requirements are met. ARM 37.86.104(3). And both state and federal courts have long accepted that certain abortions are not medically necessary, but are rather elective, nontherapeutic abortions for which state Medicaid programs do not have to pay. See, e.g., Jeannette R. v. Ellery, 1995 Mont. Dist. LEXIS 795, *26, *29 (1st Jud. Dist., May 22, 1995) (while the department is required to pay for medically necessary abortions through the Medicaid program, its decision "does not conclude that the state of Montana must fund elective, nontherapeutic abortions"; "[i]t is clear that the state need not fund nontherapeutic, elective abortions"); Maher v. Roe, 432 U.S. 464, 479-480 (1977) (upholding Connecticut regulation that required prior authorization for state Medicaid benefits for medically necessary first-trimester abortions and holding that "[i]t is not unreasonable for a State to insist upon a prior showing of medical necessity to insure that its money is being spent only for authorized purposes").

<u>COMMENT #29</u>: A commenter expressed opposition to the proposed amendment and suggested the Montana legislature established the Montana Medicaid program "for the purpose of providing necessary medical services to eligible persons who

have need for medical assistance." 53-6-101, MCA. Pregnancy care is essential medical care and abortion care, being an integral part of pregnancy care, is also essential medical care.

RESPONSE #29: Please see the response to Comment #28.

<u>COMMENT #30</u>: A commenter expressed opposition to the proposed amendment. The commenter stated the rules are a continual attack on the rights and agency of the poor and disproportionately affects marginalized groups such as people of color, indigenous, and LGBTQ+ populations.

<u>RESPONSE #30</u>: The department disagrees. The department treats all Montanans served by its programs with dignity and respect. But it is required to operate such programs, including the Medicaid program, in compliance with the statutory requirements imposed by the legislature. The rules seek to ensure, consistent with the Montana statutes governing the Medicaid program, that it covers only medically necessary abortions.

<u>COMMENT #31</u>: A commenter expressed opposition to the proposed amendment and suggests DPHHS admits that requiring preauthorization increases Montana taxpayer costs. Taxpayers should not be on the hook for supporting extreme political agendas.

<u>RESPONSE #31</u>: The potential increase in expenditures resulting from prior authorization or post-service prepayment review is necessary to ensure that the Montana Medicaid program only covers abortion services where required by federal or state law and that it is not covering elective, nontherapeutic abortions.

<u>COMMENT #32</u>: A commenter expressed opposition to the proposed amendment and stated many females are sexually victimized. These victims should not have their right to choose an abortion taken away. They are already traumatized. The choice over their body should never be taken away.

RESPONSE #32: Under the Hyde Amendment, Montana Medicaid statutes, and these rules, the Medicaid program covers abortions when the pregnancy results from rape or incest, as certified by the physician on the MA-037 form; the form does not require the woman to have reported the rape or incest to the appropriate authorities if, in the professional judgment of the physician, she was and is unable to do so. The rules do not impose any documentation requirements in addition to the completed and signed MA-037 for abortions in which Medicaid coverage is sought because the pregnancy is a result of rape or incest. The department notes that upon finalization of the rule, it will closely monitor such claims and take appropriate action if the number of claims for coverage of abortion because of rape or incest spikes and the rates for such abortions exceed historical rates.

<u>COMMENT #33</u>: A commenter expressed opposition to the proposed amendment and suggests it is a "forced birth" amendment.

<u>RESPONSE #33</u>: The department disagrees with the assertion. Under the rules, the department will continue to cover medically necessary abortions. The rule amendment intends to ensure the abortion services covered by Medicaid are medically necessary and statutorily authorized.

<u>COMMENT #34</u>: A commenter expressed opposition to the proposed amendment and suggests roughly 80% of abortions are performed before eight weeks and can be provided by a doctor or midlevel practitioner. They state that safety has been established so why limit access to doctors only.

RESPONSE #34: As discussed earlier, federal regulations prohibit the use of federal funds for abortion services unless a physician certifies in writing, in their professional opinion, the life of the mother would be endangered if the pregnancy were carried to term, or that the abortion is necessary as a result of rape or incest. 42 C.F.R. § 441.201 defines a physician as a doctor of medicine or osteopathy who is licensed to practice in the state. To ensure compliance with federal and state law, to maximize the availability of federal financial participation, to protect the integrity of the Medicaid program, and to protect the health and safety of Medicaid beneficiaries, the Medicaid program can limit Medicaid payment to services provided by certain types of health care providers. In this case, the department will not authorize payment of abortion services unless provided by a physician as defined in 37-3-102, MCA.

COMMENT #35: A commenter expressed support for the proposed amendment stating the proposed rules bring the department's rules in conformity with Jeannette R. v. Ellery to ensure general fund tax dollars are only being used to fund abortions of unborn babies when the procedure is medically necessary and to ensure that there is sufficient documentation to support that taxpayer funded abortions meet the criteria for payment by the Montana Medicaid Program. The commenter stated agreement with the contractor's recommendations and urges the department to adopt the proposed amendment as drafted. The commenter suggests the proposed amendment is not an assault on the Montana Supreme Court's decision in the Armstrong case and it ensures good financial stewardship and faithfulness for the administration of the Montana Medicaid Program. The commenter suggests requiring health care providers to provide greater specificity to medically necessary health care services is not a hindrance to health care, instead, it serves as an important verification that general fund dollars are not being used to fund unnecessary medical procedures. Funding unnecessary medical procedures ultimately reduces the funds reserved to assist qualifying individuals under Montana's Medicaid program.

<u>RESPONSE #35</u>: The department agrees and thanks the commenter for their support of the rule amendment.

<u>COMMENT #36</u>: The department received a comment in opposition stating that the commenter has an appreciation for the department's due diligence and commitment

to adhering to the Hyde Amendment and related court decisions. The commenter stated the requirement to obtain prior authorization adds additional burdens to providers and is a tactic by insurance companies to delay or discourage needed patient care. They assert that physicians spend close to 14 hours per week on prior authorizations which is one of the top administrative burdens leading to physician burnout. The commenter recommends that rather than implement prior authorization requirements the department should require providers to fill the form out in its entirety. They further state that if the department is to pursue adoption it is essential to mandate the department processes the prior authorization requests within 48 hours.

RESPONSE #36: While the department appreciates the commenter's suggestion that it require providers to complete the MA-037 form in its entirety, the department does not believe that such a requirement would be sufficient to ensure that the department is only paying for medically necessary abortions, and is not covering elective, nontherapeutic abortions. With respect to the requirement for prior authorization and the prior authorization process, please see the response to Comment #25.

<u>COMMENT #37</u>: The department received several comments stating the proposed rule amendments would limit access to necessary abortion services for women experiencing miscarriages.

<u>RESPONSE #37</u>: Consistent with the definition of abortion in Montana statutes (see, e.g., 50-20-104 and 50-20-703, MCA), a miscarriage (or spontaneous abortion) does not constitute an abortion for purposes of these rules: The rules specifically provide that prior authorization is not required for incomplete abortions, miscarriages, or septic abortions.

<u>COMMENT #38</u>: The department received several comments in opposition to the rule stating it may require a woman to continue a pregnancy, even if serious fetal abnormalities are detected. Such abnormalities may be incompatible with life upon delivery.

RESPONSE #38: The department acknowledges that, in certain instances, a pregnancy may involve fetal abnormalities. It is the department's understanding that serious fetal abnormalities that are incompatible with life upon delivery are rare. However, there is a possibility that, while the rules would not preclude a woman from obtaining an abortion, the circumstances would not meet the definition of medical necessity and, thus, Medicaid coverage would not be available. Depending on the type of fetal abnormality involved and the method of detection, there is also the possibility of misdiagnosis and/or correction of some abnormalities during fetal development. The department also notes that there may be instances where the fetal abnormality or the development of such fetus may threaten the woman's physical health, consistent with the definition of medical necessity, thus, establishing medical necessity and permitting Medicaid to cover the abortion.

<u>COMMENT #39</u>: The department received a comment in opposition to the proposed rule amendment stating the imposition of a prior authorization requirement creates an unnecessary barrier to care and that the definition of medical necessity is narrow and will lead to widespread denials. The commenter further stated that the requirement for a physical examination prohibits access to telehealth services and will disproportionally harm people living in rural areas.

<u>RESPONSE #39</u>: The department disagrees that the definition of medical necessity is unduly narrow. In defining medical necessity, the department sought to create a balanced definition that would not be overly narrow, nor overly broad, such that the definition could be used to justify Medicaid coverage of elective nontherapeutic abortions.

With respect to the requirement for prior authorizations, please see the responses to Comments #5, #19, #22, and #28.

With respect to documentation of a physical examination and the availability of telehealth, please see the response to Comment # 4.

<u>COMMENT #40</u>: The department received comments from several individuals sharing their personal stories related to how having an abortion impacted their lives.

<u>RESPONSE #40</u>: The department thanks the commenters for participating in the rulemaking process and appreciates the sharing of their personal experiences.

4. These rule amendments are effective May 1, 2023.

/s/ PAULA M. STANNARD

Paula M. Stannard Rule Reviewer /s/ CHARLES T. BRERETON

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

Certified to the Secretary of State April 18, 2023.