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MONTANA FIRST JUDICIAL DISTRICT COURT, LEWIS AND CLARK COUNTY

PLANNED PARENTHOOD OF MONTANA; et al., Plaintiffs, v. STATE OF MONTANA; et al, Defendants.	Cause No.: ADV 23–299 Honorable Mike Menahan **AFFIDAVIT OF MICHAEL RANDOL**

STATE OF MONTANA)
:ss
County of Lewis and Clark)

Michael Randol states under oath:

1. I am the Medicaid and Health Services Executive Director for the Montana Department of Public Health and Human Services ("DPHHS") and serve as the State Medicaid Director. I am over 18 years old and I have personal knowledge of the facts stated in this affidavit.

Background

2. Since the 1970s, the federal Hyde Amendment has banned the use of federal funds for abortions in State Medicaid Programs except in certain, limited circumstances. Currently, under the Hyde Amendment, only abortion services provided because of rape or incest or when the life of the mother is endangered by the pregnancy are eligible for federal financial participation ("FFP"). Abortions for any other purpose are not eligible for FFP.

3. Montana Medicaid provides guidance to providers on abortion services through the Administrative Rules of Montana and the Physician-Related Services Manual, which addresses both abortion services eligible for FFP as well as those funded with state-only Medicaid funds (medically necessary abortions where the life of the mother is not endangered).

4. Following the decision in *Jeannette R. v. Ellery*, Cause No. BDV-94-811, 1995 Mont. Dist. LEXIS 795 (1st Jud. Dist. Court, May 22, 1995), Montana Medicaid has funded abortion services where a physician has determined the procedure to be medically necessary. The court emphasized that its decision "does not conclude that the state of Montana must fund elective, nontherapeutic abortions." *Id.* at *28; *see also id.* at *4 ("this case has nothing to do with indigent women who may seek an elective abortion. . . . Not at issue are nontherapeutic elective abortions. In other words, this case has nothing to do with abortions that are not medically necessary, as that determination is made by a physician."), *29 ("It is clear that the state need not fund nontherapeutic elective abortion.").

5. The Physician-Related Services Manual provides the below guidance:

> Abortions (ARM 37.86.104)
> Abortions are covered when one of the following conditions is met:
> - The member's life would be endangered if the fetus is carried to term.
> - The pregnancy is the result of rape or incest.

- The abortion is determined by the attending physician to be medically necessary, even if the member's life is not endangered if the fetus is carried to term.

A completed Medicaid Healthcare Programs Physician Certification for Abortion Services (MA–37) form must be submitted with every abortion claim or payment will be denied. This form is the only form Medicaid accepts for abortion services. Complete only one section of this form.

The form required for abortions can be found on the Provider Information website under Forms in the site index in the left menu of the Provider Website.

When using mifepristone (Mifeprex or RU 486) to terminate a pregnancy, it must be administered within 49 days from the beginning of the last menstrual period by or under the supervision of a physician who:

- Can assess the duration of a pregnancy.
- Can diagnose ectopic pregnancies.
- Can provide surgical intervention in cases of incomplete abortion or severe bleeding, or can provide such care through other qualified physicians.
- Can assure access to medical facilities equipped to provide blood transfusion and resuscitation.
- Has read, understood, and explained to the member the prescribing information for mifepristone.[1]

6. For abortions eligible for Medicaid coverage, a completed Medicaid Healthcare Programs Physician Certification for Abortion Services ("MA–37") form must be submitted with every abortion claim or payment will be denied.

7. The form provides three options for certification by the physician performing the abortion to support Medicaid coverage: (1) the abortion is necessary to save the member's life; (2) the pregnancy resulted from rape or incest; or (3) the abortion is medically necessary, but the member's life is not endangered, with space to provide an optional explanation. A true and correct copy of the MA–37 form is attached as **Exhibit 1**.

8. The form does not require the submission or attachment of additional documents for any of the three options for Medicaid coverage certification.

[1] *See* https://medicaidprovider.mt.gov/manuals/physicianrelatedservicesmanual.

9. Prior to the adoption of the Rule that is the subject of this litigation, a provider was only required to submit the MA-37, in addition to the standard claim form (or its electronic equivalent), in order to obtain payment for abortion services provided to an eligible Medicaid beneficiary.

10. The response on the MA–37 form allows Montana Medicaid to assign the correct fund code. When the form indicates rape or incest, or life of the mother, the abortion service is eligible for FFP. If the abortion is for any other medically necessary reason, the abortion service is funded exclusively by the state general fund.

Legislative Reporting and Findings

11. The 2021 Montana Legislature directed DPHHS to review and report on the history, utilization data, policies, rules, and definitions for Medicaid-reimbursed abortions.

12. During the September 2021 meetings of the Interim Budget Committee for Section B and the Children, Families, and Health and Human Services Interim Committee, DPHHS presented a summary of current laws, rules, policies, procedures, and claims estimates associated with Medicaid reimbursed abortions titled "Abortion Services and Montana Medicaid." A true and correct copy of this report is attached as **Exhibit 2**.

13. The report indicated claims accompanied by an MA–37 form were automatically paid, but no substantive review or auditing of claims for abortions was conducted.

14. The Interim Committees requested that DPHHS conduct an in-depth review of abortion claims paid by Montana Medicaid, as well as a legal review of the current law concerning Medicaid-reimbursed abortions.

15. DPHHS, using a contractor, reviewed all Medicaid-reimbursed abortions for which DPHHS claimed FFP for the 10-year period, July 2011 through June 2021 (6 abortions), as well

as 10% of the abortions paid for by Montana Medicaid, using only state funds, based on medical necessity for the 3-year period, July 2019 through June 2021 (79 claims for SFY 2019, 67 claims for SFY 2020, and 75 claims for SFY 2021).

16. In September 2022, DPHHS presented the results of this analysis, concluding that the information submitted on the MA–37 form lacks sufficient information to verify medical necessity, to the Interim Budget Committee for Section B.

17. With respect to medically necessary abortions, DPHHS's contractor reported that the MA–37 forms contained a brief narrative, but only 11.31% (25 claims, submitted by one provider) contained additional documentation.

18. Such additional documentation typically correlated with the vague medical condition of "complications of unintended pregnancy," or an assessment of the situation, rather than documentation to support a medical complication or disease other than the pregnancy itself.

19. The four conditions routinely indicated on the MA–37 form were: (1) pain and suffering (47.5%); (2) emotional stability (24.43%); (3) mental and physical health (9.05%); and (4) complications of unintended pregnancy (19.00%).

20. Ninety claims related to medication/chemical abortions, but only 10 of such claims included documentation establishing that the requirements of the Physician-Related Services Manual for medication/chemical abortions were met.

21. The results of the in-depth, contractor-conducted review of Medicaid-reimbursed abortion claims caused DPHHS grave concern, especially with respect to medically necessary abortions funded only by State funds. The consistent lack of documentation, coupled with the conditions routinely provided on the MA–37 forms as the basis for medical necessity, led DPHHS

to reasonably believe that Medicaid is paying for abortions that are not actually medically necessary, but are, in fact, elective, nontherapeutic abortions.

22. Moreover, if Medicaid-reimbursed abortion claims were audited, by the federal government or otherwise, DPHHS would not have sufficient documentation to support that the abortions meet the criteria for payment by the Medicaid program, regardless of whether FFP is available pursuant to the Hyde Amendment. For example, if state-funds-only abortions were audited, DPHHS would not have sufficient documentation to establish that the abortions were medically necessary. Similarly, if the federal government were to audit abortions for which FFP was claimed, DPHHS may not have sufficient documentation to establish that the abortions met the requirements of the Hyde Amendment.

23. DPHHS's contractor recommended that Medicaid-funded abortion claims should be supported by documentation, including a brief history and physical examination with evidence of the medical diagnosis and/or condition necessitating abortion, an estimate of gestational age, and corroborating laboratory and imaging studies that support the medical diagnosis or patient condition, with such additional information being submitted on (or with) the MA–37 form.

24. These concerns led DPHHS to adopt the Rule that is the subject of this litigation.

Purpose of the Rule

25. The purpose of the requirements in the Rule—the definition of medical necessity, prior authorization/prepayment review, documentation requirements, etc.—is to ensure that the abortions Medicaid pays for are medically necessary (not elective and nontherapeutic), consistent with the Montana Medicaid statute's limitation on payment for medical services and meet appropriate clinical requirements to ensure the health and safety of the Medicaid beneficiary receiving the abortion.

26. Faithfulness to the scope of the Medicaid program, as established by the Legislature, and to Montana taxpayers and state funds justifies DPHHS's decision to require the submission of documentation to support Medicaid payment for abortion services and to provide greater specificity as to what constitutes medically necessary services and the documentation needed to support such abortion payment claims. Such requirements are not uncommon and are applied to other Medicaid-reimbursed services to ensure program integrity.

27. The Rule is reasonably necessary to ensure Medicaid program integrity, to protect the health and safety of Medicaid beneficiaries, and to ensure that Medicaid only pays for medically necessary abortions and not elective, nontherapeutic abortions.

Prior Authorization and Documentation

28. The Rule requires prior authorization on abortion services to ensure covered services are consistent with the Hyde Amendment (where the pregnancy endangers the life of the mother or the pregnancy results from rape or incest) or are medically necessary and the appropriate funds are utilized.

29. To ensure that Montana Medicaid is only paying for abortions where required by federal or state law—and, thus, is not paying for elective, nontherapeutic abortions consistent with case law—the Rule requires prior authorization or post-service, prepayment review of claims for such services.

30. Requests for authorization must be submitted electronically to DPHHS's contracted Quality Improvement Organization through the Qualitrac Portal. DPHHS recognizes, however, that there may be instances where a physician seeks Medicaid reimbursement for abortion services where—because of an emergency situation or otherwise—prior authorization was not obtained. In such circumstances, the Rule requires post-service, prepayment review of the claim for payment

for the abortion service for the same reasons. Any request for prior authorization or any claim for payment for abortion services that did not receive prior authorization must be accompanied by a completed and signed MA–37 form.

31. It is not unusual for prior authorization to be required for certain services. Prior authorization is required for Medicaid coverage of many medical services and medical products, including, but not limited to:

- Wheel chairs
- Hearing aids
- Physician administered drugs, such as Sublocade, a medication for opioid use disorder
- Breast augmentation
- Transcranial magnetic stimulation, a procedure for treatment resistant depression
- Out of state inpatient hospital stays

32. It is DPHHS's practice to require prior authorization especially when there may be questions as to whether the service is medically necessary. For example, physician services for conditions or ailments that are generally considered cosmetic in nature are generally not covered by Medicaid. DPHHS requires prior authorization for such services, and limits Medicaid coverage to such cases "where 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." Admin. R. Mont. 37.86.104. This imposes a stricter test for coverage of such services than would be imposed under the general definition of "medical necessity" or "medically necessary service" that is otherwise applicable to health care services covered by Medicaid.

33. Where Medicaid payment is sought for an abortion based on medical reasons—whether the physician concludes that the life of the mother will be endangered if the unborn child is carried to term or that the abortion is otherwise medically necessary—the Rule requires certain clinical documentation, in addition to the completed and signed MA–37 form, in order to document

and justify the physician's conclusion and support appropriate reimbursement. This additional documentation is not required for abortions in which Medicaid coverage is sought because the pregnancy is a result of rape or incest.

34. The Rule requires documentation of (1) the woman's medical history; (2) brief review of systems to identify symptoms a patient may be experiencing; (3) the results of a physical examination, including estimate of gestational age (if imaging is not available); (4) results of laboratory tests (if available); (5) imaging (if available), to estimate gestational age; (6) documentation that the diagnosis of the physical or psychological condition leading to the medical necessity determination has been made by a medical professional qualified by education, training, and/or experience to make such a diagnosis and that the woman is receiving care for such condition; (7) reason for the abortion procedure; (8) for medication/chemical abortions, documentation confirming review of contraindications, adequate patient education, and compliance with the requirements of the Physician-Related Services Manual; (9) treatment plan; and (10) signed informed consent for the proposed abortion procedure.

35. Unless a health insurer, such as Medicaid, pays all claims without regard to waste, fraud or abuse—or without regard to whether a health care or related service is medically necessary—it may be necessary to interact with patients and/or their health care providers and it may be necessary to impose conditions on coverage of certain health care or related services. For example, health insurers, including Medicaid, use tools such as step therapy (where an insurer requires a patient to try a lower cost prescription drug (or treatment) for a condition before "stepping up" to a similar-acting, but more expensive drug (or treatment)), required use of generic drugs, utilization management, post service utilization review, and review of medical records to

verify that payments for health care services are appropriate and consistent with the applicable laws and insurer obligations.

36. Medicaid has ongoing relationships with—and responsibility to—Medicaid beneficiaries, including those pregnant women who choose an abortion. While Medicaid cannot cover abortions that are not medically necessary, if an abortion is medically necessary because of a physical or mental health condition, Medicaid could be responsible for covering the necessary treatment to address the condition.

37. The Rule requires documentation that the diagnosis of the physical or psychological condition leading to the medical necessity determination has been made by a medical professional qualified by education, training, and/or experience to make such diagnosis and that the woman is receiving care for such condition.

38. This requirement ensures the accuracy of the diagnosis on which the conclusion of medical necessity rests and, thus, provides assurance that the Montana Medicaid program is not paying for elective, non-therapeutic abortions.

39. The documentation also establishes that the safety and wellbeing of the female patient has been considered. The assessment, including physical examination and imaging (with a determination of gestational age) is especially important when medication/chemical abortions are being performed.

40. As with the requirement for prior authorization or post-service, prepayment review, it is not unusual for DPHHS to require providers to submit additional documentation, clinical or otherwise, to support their claim that particular services are covered by Medicaid and that the particular claim should be paid. By the nature of the Medicaid program, the Medicaid provider is required to do the appropriate paperwork, the obligation is not on the Medicaid member. For

example, DPHHS requires the submission of documentation by the Medicaid provider to support claims for Medicaid payment of the following services:

- Targeted case management
- Out-of-state inpatient hospital stays
- Certain prescription medications.
- Orthodontia
- Hearing aids
- Ambulance transports
- Botox injections

41. States cannot claim FFP for abortion services unless a physician certifies in writing that, 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. Abortion is a type of service that, in one situation, may be medically necessary and therapeutically appropriate, but may not be medically necessary and an elective service in another situation. The Montana Medicaid Program needs a documentary process to establish which abortions are eligible for coverage as medically necessary.

Provider Requirements

43. To ensure with federal regulations (42 CFR Part 441 (Subpart E – Abortions)), the Rule limits abortion services to those services rendered by a physician.

44. 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.

45. If a pregnant Medicaid beneficiary experiences adverse effects of a surgical or medication/chemical abortion—whether the adverse effects are physical or psychological and whether they occur immediately or do not manifest themselves for some time after the abortion—Medicaid would be responsible for providing coverage for the necessary physical and/or mental

health services to treat or mitigate those adverse effects, for as long as the beneficiary remains eligible for such Medicaid services.

46. Medicaid, thus, has an interest in ensuring that its pregnant Medicaid beneficiaries receive abortion-related care directly from health care professionals who have the skills necessary to provide a high level of care.

47. Given Medicaid's statutory obligation and responsibility to only pay for medically necessary services, and that it has not been receiving sufficient documentation to confirm providers' medical necessity claims, it must have a mechanism for getting the necessary documentation.

48. Requiring documentation contemporaneous to the abortion service is the most effective time for the abortion provider to generate the required documentation and it ensures that the abortion provider has a fair opportunity to obtain the required documentation, as opposed to trying to obtain or generate supporting documentation after the procedure has been performed.

49. Assuming that the abortion provider is accurately assessing and documenting medical necessity, the risk that an abortion claim would be rejected in post-service prepayment review is no greater than the risk that Medicaid (or any other insurer) would determine that a service is unnecessary or otherwise not covered and, thus, deny payment.

50. All Medicaid providers run the risk that Medicaid, based on review of a claim by its utilization review contractor, will determine that a service is not medically necessary and either deny payment of the claim or seek recoupment of a previously paid claim.

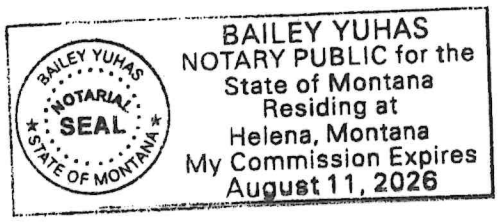
DATED this 12th day of May, 2023.

MICHAEL RANDOL

STATE OF MONTANA)
:
County of Lewis and Clark)

Subscribed and sworn to before me, a Notary Public, this 12th day of May, 2023 by Michael Randol.

(S E A L)



Bailey Yuhas

Notary Public for the State of Montana