SENATE BILL 535 — MONTANA'S EXPANDED RIGHT TO TRY

Experimental Treatment in Montana: What It Means for You

Montana is the first state where a drug, biologic, or device that has finished its first FDA safety trial can be given to patients outside a clinical trial — and you do not have to be terminally ill to ask for it. This guide explains, in plain terms, what the law allows, what protections you have, what it will cost you, and what to ask before you sign anything.

Phase I
MINIMUM FDA TRIAL A TREATMENT MUST HAVE COMPLETED

Not yet
FDA-APPROVED — THESE ARE EXPERIMENTAL TREATMENTS

Cash-pay
ASSUME INSURANCE WILL NOT COVER ANY OF IT

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CENTERS LICENSED SO FAR — NOTHING IS OPEN TO PATIENTS TODAY

Where Things Actually Stand

Status as of August 21, 2026

The law is real and the rules are final — but no center is open and no patient has been treated.

- ✓ MAY 12, 2025 · **SB 535 signed into law**, effective immediately. Montana becomes the first state to authorize licensed Experimental Treatment Centers for therapies that have cleared FDA Phase I.
- ✓ JULY 25, 2026 · **State rules took effect.** DPHHS adopted 25 rules (ARM 37.106.3301–3325, MAR Notice 2026-427.2) setting out how a center gets licensed and how patients must be protected.
- ✓ JULY 25, 2026 · **A private review board formed.** The Montana Experimental Treatment Review Board — a private board, not a state agency — began accepting treatment applications from companies. Two are under review (a peripheral-neuropathy therapy and a hearing-loss therapy).
- • **Still ahead: no center is licensed yet.** As of this printing, DPHHS has not licensed a single Experimental Treatment Center, no treatment has been approved by a review board, and no patient has been treated under SB 535.

If someone tells you they can treat you in Montana under SB 535 right now, that is not accurate. Before paying anyone anything, ask for the center's DPHHS license number and verify it with the state. A clinic that cannot produce one is not operating under this law.

Who Can Be Treated, and Under What Conditions

✓ What the law opens up

- **No terminal diagnosis required.** Earlier right-to-try laws were limited to terminal illness. Montana's is not.
- Open to **any patient who gives informed consent and can pay** — including out-of-state and international patients.
- Covers drugs, biologics, and devices that have **completed phase 1 of a clinical trial** and are not yet FDA-approved, and that either remain in an FDA-approved trial or carry a documented safety record from a qualified medical institution.
- Some low-risk treatments may be given **outside the center** if the review board finds it safe — intended to help rural patients.

⊘ What still has to be true

- The center must hold a **current DPHHS license**. Treatment outside a licensed center is not covered by this law.
- An **independent review board must approve the protocol** before any patient receives it.
- You must document that you have **evaluated the FDA-approved options** for your condition — you need not have failed them, but you must have considered them.
- You need a **history and physical within 30 days** of starting, plus pre-treatment screening.
- You must sign a written consent that spells out the treatment, its trial phase, and **every cost**.

A Phase I trial answers one narrow question: **did a small group of people tolerate this at these doses, for a short time?** It is not designed to show that a treatment works, and it does not rule out harms that appear later or in sicker patients. Everything on the next page follows from that single fact.

YOUR PROTECTIONS, THE REAL RISKS, AND WHAT TO ASK

Before You Say Yes

Protections the Rules Give You

Informed Consent

- Must name the treatment, its form, and the **clinical trial phase** it has reached
- Must disclose **all costs to you**, in writing, before treatment
- Must include the full text of Montana's immunity-from-suit law (50-12-110, MCA)
- Must include the center's patient grievance policy

Independent Review Board

- **At least five members**, including a Montana-licensed physician, an outcomes researcher, and an ethicist
- No personal, financial, employment, or ownership stake in the center it reviews
- Must approve **every protocol** before any patient is treated; meets at least monthly
- Publishes an annual public report including **aggregate patient outcomes**

If Something Goes Wrong

- Serious adverse events — death, life-threatening events, hospitalization, major incapacity — reported to **both the state and the review board within 5 days**
- A **hospital transfer agreement** for emergencies is a condition of licensure, and a Montana-licensed medical director serves as safety officer

Oversight & Access

- Centers file an annual quality and adverse-event report with the state **by February 1**; late filing can reduce the license
- Statute directs **2% of a center's net annual profits** toward improving Montanans' access — collection mechanics are still being worked out

Risks You Should Weigh Honestly

! **Passing Phase I is not proof of safety.** Harvard Medical School's Dr. Aaron Kesselheim has noted that roughly one in six drugs that clear Phase I later turn out to have safety problems — and Phase I says nothing at all about whether a treatment works.

$ **Prices are not regulated and insurance will almost certainly not pay.** A center and manufacturer may charge whatever they choose — no cap, no negotiated rate, no published price list — and your plan is unlikely to cover the treatment or complications from it. Ask them in writing before you commit.

§ **You give up legal recourse.** Montana's immunity statute limits who can be sued if you are harmed. That statute's full text must appear in your consent form — read that section closely, ideally with a lawyer.

? **The federal picture is unsettled.** The FDA has taken no public position on Montana's framework, and preemption questions remain open. A future federal decision could change what is available.

✓ **Free alternatives may exist.** You may qualify for an actual clinical trial (ClinicalTrials.gov) or the FDA's expanded access program, where the treatment is typically provided at no charge and with fuller monitoring. Ask about both first.

Eight Questions to Ask Before You Consent

1. What exactly is this treatment, and **where can I read the Phase I results?**
2. What is the **total cost** — treatment, monitoring, follow-up, travel, complications?
3. What is this center's **DPHHS license number**, and may I verify it with the state?
4. Which review board approved this protocol, and **who sits on it**?
5. Do I qualify for a **clinical trial or FDA expanded access** instead, at no cost?
6. If I have a serious reaction, **who treats me, where, and who pays** for it?
7. What **FDA-approved options** exist for my condition, and why is this better?
8. What outcomes have prior patients had? **Show me the board's public report.**

Take the Form Home

Nothing in this law requires you to decide on the spot. Ask for the consent form in advance, read it away from the clinic, and bring it to your own physician and, if money or liability is involved, to a lawyer. A center operating in good faith will expect you to do exactly that — and will still be there next week.

Verify a license: Montana DPHHS, Quality Assurance Division — dphhs.mt.gov · **Find a real trial:** search your condition at ClinicalTrials.gov and ask your doctor about FDA expanded access · **Learn more:** montanabio.org

Prepared by the Montana BioScience Alliance for patient education. Current as of August 21, 2026, and based on SB 535 (2025, Ch. 621) and the implementing rules ARM 37.106.3301–3325, adopted by MAR Notice 2026-427.2 effective July 25, 2026. This is general information, not legal or medical advice, and it is not an endorsement of any treatment, company, or provider. Treatments offered under SB 535 are experimental and not FDA-approved; they are cash-pay and prices are unregulated. As of this printing no Experimental Treatment Center has been licensed by the State of Montana and no patient has been treated under this law. Requirements and center status change — verify current information with DPHHS, your physician, and qualified counsel before making any decision.