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ADVANCING IMPACT ON MATERNAL  
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# **Classifying Mifepristone, Misoprostol, and Methotrexate as Controlled Substances: Patient Care Consequences and Clinical Implications**

## **Key Issues and Policy Considerations**

### **Policy Brief**

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## KEY TAKEAWAYS

### Executive Summary

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This brief examines the trend of states designating mifepristone, misoprostol, and methotrexate as controlled substances and documents a pattern of clinical disruption that has been shown to extend well beyond the abortion debate. Louisiana's experience under Act 246<sup>1</sup> has produced measurable harm to patients seeking miscarriage care, hemorrhage treatment, and routine gynecologic services, harm that a state court has found sufficient to support a constitutional challenge. Legislative proposals have been proposed in South Carolina, Texas, Kentucky, Mississippi, Missouri and Iowa that would expand this framework through additional mechanisms of restriction, liability, and criminal exposure for clinicians who prescribe medications with established, broad medical utility.

Mifepristone, misoprostol, and methotrexate are medications that are prescribed across emergency medicine, obstetrics, rheumatology, and oncology for indications that are unrelated to elective abortion. Legislation attempting to restrict access to these medications for one clinical indication (elective abortion) does not account for this reality and creates barriers to care that extend across specialties and patient populations.

The recommendations in this brief are grounded in existing clinical standards, documented public health outcomes, and the established positions of major medical organizations. Legislators considering these issues are encouraged to review the Louisiana data before advancing similar proposals, to ensure that any legislation includes meaningful safe harbor protections for clinicians acting within the standard of care, and to require impact assessments so that the public health consequences of existing restrictions are systematically measured and reported.

### Take Home Points

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- ▶ **Broad Medical Utility Beyond Abortion:** Mifepristone, misoprostol, and methotrexate are essential medicines used across emergency medicine, obstetrics, rheumatology, oncology, and other medical specialties for conditions unrelated to elective abortion, including postpartum hemorrhage, miscarriage management, ectopic pregnancy, cancer, and autoimmune disease.
- ▶ **State Reclassification is Not Evidence-Based:** Several states are trying to classify these medications as Schedule IV controlled substances despite the fact that none are associated with dependence, tolerance, or abuse potential, as required by law. The American College of Medical Toxicology has formally stated this reclassification is clinically unjustified.
- ▶ **Statutory Exemptions Do Not Prevent Clinical Hesitation:** Documented cases in Florida and Texas show that clinicians and pharmacists withhold these medications out of legal uncertainty, even where legislation explicitly permits non-abortion uses.

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<sup>1</sup> [ACT No. 246](#)

- ▶ **Louisiana Provides a Real-World Cautionary Model:** Louisiana's Act 246 has produced documented harm: locked storage requirements caused up to 10-minute delays in hemorrhage response, nearly half of surveyed pharmacies stopped stocking misoprostol, and patients were denied medication for miscarriage management and cancer diagnosis (endometrial biopsy).
- ▶ **State Legislative Activity Is Expanding:** Following Louisiana's legislative success, bills have been proposed in South Carolina, Mississippi, Texas, Kentucky, Missouri and Iowa through controlled substance reclassification, drug trafficking charges, mandatory in-person dispensing, and civil liability frameworks.

**Recommendations:** State legislatures should not reclassify these medications as controlled substances, as the clinical evidence does not support that designation. Where reporting requirements exist, they should be repealed or revised to remove prescriber-identifying information. States that have already enacted restrictions should commission independent public health impact assessments to evaluate consequences for patient care and commit to repeal the restrictions if findings demonstrate clinical harm.

## BACKGROUND

### The Essential Role of Mifepristone, Misoprostol, and Methotrexate

While often discussed in the context of elective abortion, mifepristone, misoprostol, and methotrexate are staples of modern medicine with broad, well-established clinical applications both in and out of reproductive health care.

Mifepristone is a synthetic steroid that blocks progesterone receptors and results in bleeding and disruption of the endometrium. Mifepristone is approved by the U.S. Food and Drug Administration (FDA) for two entirely distinct indications: pregnancy termination (in combination with misoprostol), and the treatment of Cushing's syndrome, a life-threatening condition caused by prolonged excess cortisol. It is used off-label for numerous indications, including medication management of miscarriage to ensure the uterus is emptied to prevent serious infections and sepsis, emergency contraception, and adjunct therapy for uterine fibroids.<sup>2</sup> Mifepristone is also being studied for use in the treatment of gynecologic cancers, such as ovarian and endometrial cancer.<sup>3</sup>

Misoprostol is a synthetic prostaglandin analogue that is used for numerous indications in the practice of obstetrics and gynecology and is on the World Health Organization's Essential Medicines List because of its critical role in preventing maternal mortality. While marketed as a medication to prevent and treat intestinal damage induced by nonsteroidal anti-inflammatory drugs (NSAIDs), it is used off-label for the induction of labor, cervical preparation before surgical procedures such as IUD insertion or endometrial biopsies, medication management of

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<sup>2</sup> [Selective progesterone receptor modulators in reproductive medicine: pharmacology, clinical efficacy and safety - PubMed](#)

<sup>3</sup> [Mifepristone - StatPearls - NCBI Bookshelf](#)

miscarriage, and the treatment of postpartum hemorrhage, the leading cause of maternal mortality worldwide. Misoprostol is less expensive than mifepristone, available worldwide, has a long shelf life, and does not need refrigeration.<sup>4</sup>

Methotrexate is a folate antagonist that disrupts rapidly dividing cells and is used for many indications. It is the only medication option to treat an ectopic pregnancy, a life-threatening condition when a fertilized egg implants somewhere other than viable uterine tissue. Without methotrexate, patients may require surgical treatment of an ectopic pregnancy, which can lead to loss of fertility. Methotrexate is also an essential treatment for several disorders, including rheumatoid arthritis, juvenile idiopathic arthritis, and refractory psoriasis. It is also one of the primary chemotherapy choices for several types of cancer, including acute lymphoblastic leukemia and relapsed or refractory non-Hodgkin lymphoma.<sup>56</sup>

All three of these drugs are on the World Health Organization's Essential Medicines List<sup>7</sup> because they play such a critical role in any functioning health system that they should be available and accessible at all times.

## **Current Guidance under the Food and Drug Administration**

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Since approval, the FDA has maintained that these medications are safe and effective. However, mifepristone, misoprostol and methotrexate are subject to different levels of regulation and oversight.

### **FDA's Risk Evaluation and Mitigation Strategy Program**

#### **Mifepristone**

Mifepristone is regulated under a Risk Evaluation and Mitigation Strategy (REMS),<sup>8</sup> a program reserved for drugs with known serious risks requiring active management beyond standard labeling. Despite an extensive body of research demonstrating mifepristone's safety, it remains subject to a REMS, not because of clinical evidence of harm, but because of political controversy over its use for abortion. The REMS has been modified multiple times but continues to impose burdensome requirements on every prescriber, pharmacy, and patient involved in dispensing the drug.

It is worth noting that the American College of Obstetricians and Gynecologists (ACOG) and other major medical organizations have consistently characterized these REMS requirements as a medically unnecessary barrier to safe, essential reproductive health care that is not based on clinical evidence, and that disproportionately burdens communities already facing structural barriers, including people of color and those in rural areas and medically underserved communities.<sup>9</sup> No comparable REMS exists for drugs with similar safety risk profiles in other therapeutic categories.

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<sup>4</sup> [Uses of misoprostol in obstetrics and gynecology - PubMed](#)

<sup>5</sup> [Methotrexate - StatPearls - NCBI Bookshelf](#)

<sup>6</sup> [Ectopic Pregnancy - StatPearls](#)

<sup>7</sup> [The selection and use of essential medicines. 2025: WHO Model List of Essential Medicines. 24th list](#)

<sup>8</sup> [Risk Evaluation and Mitigation Strategies | REMS | FDA](#)

<sup>9</sup> [Updated Mifepristone REMS Requirements | ACOG](#)

The practical workflow under the current REMS looks like this: A clinician who wishes to prescribe mifepristone cannot simply write a prescription. They must first be a provider who has completed and submitted a Prescriber Agreement Form under the shared REMS system for mifepristone, which is maintained by the three approved drug sponsors of mifepristone (Danco Laboratories, GenBioPro, and Evita). This “certification” is an ongoing agreement that the prescriber is responsible for implementing and maintaining compliance with the REMS program.<sup>7</sup> The clinician must submit this form to every pharmacy where they may prescribe, each hospital inpatient pharmacy and any retail pharmacy their patients might use. If the form is not on file, the prescription will not be filled. If the medication is out of stock, the patient cannot simply go to another pharmacy; they are limited to pharmacies where their provider has already registered, regardless of availability elsewhere.

On the patient side, the Patient Agreement Form must be reviewed with and signed by both the patient and the healthcare provider, and the risks of the mifepristone treatment regimen must be fully explained before mifepristone is prescribed. The patient must also be provided with a copy of the signed form and the FDA-approved Medication Guide. The signed form is then placed in the patient’s medical record. Patients are instructed to bring the Medication Guide with them to any emergency room visit so that providers unfamiliar with the regimen are informed.

The dispensing pathway expanded meaningfully in 2023. The FDA permanently removed the in-person dispensing requirement under the REMS, which had previously confined mifepristone distribution to clinics, medical offices, and hospitals, and added a new pharmacy certification process, enabling retail pharmacies (both brick-and-mortar and mail-order) to dispense mifepristone directly to patients who have a prescription from a certified prescriber.<sup>10</sup> However, retail pharmacies are not automatically eligible to dispense mifepristone. Any pharmacy, including online pharmacies, seeking to dispense mifepristone must complete a Pharmacy Agreement Form and designate an authorized representative responsible for overseeing implementation and compliance with the REMS program. Pharmacies must also verify prescriber certification before dispensing and are required to ensure the drug reaches the patient within four calendar days of receiving the prescription; if delivery will be delayed beyond four days, because of the REMS agreement, the pharmacy must notify the certified prescriber to confirm that dispensing remains appropriate.

### **Misoprostol & Methotrexate**

Misoprostol and methotrexate are not under an FDA REMS program. They are historically non-controlled substances with broad, off-label uses in gynecology, oncology, rheumatology, and emergency obstetrics. They are prescribed and dispensed like any other unrestricted prescription medication, used for FDA-approved and off label conditions.

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<sup>10</sup> [Updated Mifepristone REMS Requirements | ACOG](#)

# RESTRICTING ACCESS TO ESSENTIAL MEDICINES

## **State-Level Reclassification of Mifepristone and Misoprostol**

Several states have moved to reclassify mifepristone and/or misoprostol as Schedule IV Controlled Dangerous Substances (CDS), placing them in the same regulatory category as Xanax (alprazolam) and Valium (diazepam), benzodiazepines with well-documented addiction, physical dependence, and abuse potential. The comparison is medically illogical. Benzodiazepines are scheduled precisely because they carry risks of tolerance, withdrawal, misuse, and overdose. Mifepristone and misoprostol have none of those properties as neither produces euphoria, physical dependence, or withdrawal syndromes, and neither has a recognized pattern of recreational misuse or diversion.

The clinical consequences of reclassification are not theoretical. Louisiana's experience under Act 246 has documented them in real patients with measurable harm.

## **Evidence of Clinical Harm: Lessons From Louisiana**

Louisiana's experience as the first and only state to enact Schedule IV reclassification of misoprostol and mifepristone under Act 246 provides real-world evidence that restricting these drugs delays and denies care for conditions affecting patients who are not seeking abortion services. The harm cascades from obstetric emergencies into miscarriage management, routine gynecologic care, the treatment of ectopic pregnancy, and the treatment of rheumatological conditions.

### **Emergency Obstetric Care**

Misoprostol has been used for decades to control postpartum hemorrhage<sup>11</sup> and in Louisiana was previously stored on bedside hemorrhage carts, accessible in under a minute. Act 246 moved misoprostol to locked automated dispensing cabinets. In advance of the law taking effect, a New Orleans hospital conducted timed drills documenting retrieval times exceeding two minutes; once the law was in force, one OB/GYN reported a retrieval time of nearly 10 minutes during an active hemorrhage. In a postpartum hemorrhage, blood loss can exceed half a liter per minute, with hemorrhagic shock possible within minutes and death within ten minutes without intervention. In December 2024, a Louisiana patient undergoing an emergency cesarean section experienced a delayed misoprostol retrieval while actively hemorrhaging and asked her anesthesiologist: "Is this how I'm going to die?"<sup>12</sup>

The delays created by Act 246 directly violate the Alliance for Innovation on Maternal Health (AIM) Obstetric Hemorrhage Patient Safety Bundle, a nationally adopted, evidence-based framework developed to standardize hospital responses to obstetric hemorrhage. The Bundle

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<sup>11</sup>[Practice Bulletin No. 183: Postpartum Hemorrhage - PubMed](#)

<sup>12</sup>[Evaluating the Impact of Act 246 of the 2024 Louisiana Legislative Session: The Classification of Misoprostol and Mifepristone a](#)

requires that hemorrhage carts be stocked and immediately accessible at the bedside, with medications that cause uterine contractions (including misoprostol) available for administration without delay at the time of hemorrhage recognition. Requiring pharmacy dispensing under controlled substance protocols before misoprostol can be accessed breaks the emergency response chain the Bundle is designed to protect, converting a life-saving intervention into a bureaucratic transaction at the moment when seconds determine survival. Before Act 246, Louisiana's adherence to the AIM Obstetric Hemorrhage Bundle was working. Severe maternal morbidity from postpartum hemorrhage had fallen by nearly 40% between 2018 and 2020, a direct result of the standardized, immediate access to medications outlined in the Bundle.<sup>13</sup> Reclassifying misoprostol as a controlled substance dismantles the very infrastructure that drove those gains.

Maternal mortality is a national crisis, the United States has the highest maternal death rate of any high-income country,<sup>14</sup> and Louisiana ranks among the worst in the nation. Against that backdrop, Dr. Veronica Gillispie-Bell, Louisiana's state maternal mortality director, stated that Act 246 'endangers' women and increases the risk they 'will bleed out after childbirth,'<sup>15</sup> a warning issued not by an advocate, but by the physician the state itself appointed to track and prevent these deaths

### **Miscarriage Management and Routine Gynecologic Care**

The disruption extends well beyond the delivery room. Misoprostol is a first-line treatment for miscarriage management, and mifepristone combined with misoprostol is the ACOG-recommended standard of care for incomplete and early pregnancy loss.<sup>16</sup> Following Act 246, the New Orleans Health Department (NOHD)<sup>17</sup> survey found almost half of the pharmacies in Orleans and Jefferson Parishes did not stock misoprostol, with a third of those admitting they had stocked the medication prior to the new law. The report describes patients who were denied misoprostol at the pharmacy despite needing it for miscarriage management or cancer screening.

In October 2024, *Birthmark Doula Collective v. Louisiana* was filed challenging Act 246 on the grounds that it violates the Louisiana Constitution by discriminating based on physical condition. In May 2025, a state court judge ruled that plaintiffs had sufficiently demonstrated harm to proceed with their constitutional challenge to the law—an independent judicial finding that the access failures documented by NOHD reflect real, legally cognizable injury.

### **Statutory Exemptions Do Not Prevent Clinical Hesitation**

Louisiana's Act 246 shows us that restrictions that do not outright ban a medication still have the effect of limiting access. Act 246 only purported to make the medication a Schedule IV drug,

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<sup>13</sup> [Improving and Maintaining Reductions in Severe Maternal Morbidity Through a Statewide Perinatal Quality Collaborative](#)

<sup>14</sup> [Maternal Mortality in the United States: A Primer](#)

<sup>15</sup> [Doctors Seek More Guidance From Louisiana Officials As New Maternal Care Drug Law Takes Effect | Pulitzer Center](#)

<sup>16</sup> [Methods for managing miscarriage: a network meta-analysis - Ghosh, J - 2021 | Cochrane Library](#)

<sup>17</sup> [Evaluating the Impact of Act 246 of the 2024 Louisiana Legislative Session: The Classification of Misoprostol and Mifepristone a](#)

which means that it should still be accessible, just with additional administrative constraints. In reality, pharmacies stopped carrying the medication and it became inaccessible for many patients. Even a law designed to narrowly target use of medications for abortion will have broader impacts on patient care across a range of conditions, particularly on such a highly politicized issue where providers fear legal liability.

Delays in care for patients needing treatment for ectopic pregnancy, which would be the case in a methotrexate restriction, are well documented, despite the care being explicitly legal in most states with abortion bans.<sup>18</sup> A September 2024 Physicians for Human Rights report documented additional cases in Florida in which ER staff refused to administer methotrexate for ectopic pregnancies, describing it as an “abortive agent.”<sup>19</sup> In Texas, two women filed federal complaints after hospitals refused to administer methotrexate for ectopic pregnancies despite the fact that such treatment is explicitly permitted under Texas law. In one case, the pregnancy ruptured before the hospital agreed to intervene; the patient required emergency surgery and lost a fallopian tube.<sup>20</sup>

Although South Carolina's H. 4760<sup>21</sup> explicitly exempts methotrexate from reclassification when used to treat an ectopic pregnancy, we have already seen the harm that follows when barriers are placed between patients and legally allowable reproductive care. These additional restrictions will only deepen the chilling effect on clinical practice, as demonstrated by the experiences of women in Florida and Texas, where providers delayed or withheld treatment even when exceptions clearly applied.

Attempts to re-classify these medications as controlled substances are not evidence based, they are a policy mechanism that enables states to require in-person dispensing, restrict mail-order delivery, and create new criminal exposure for prescribers and pharmacists, adding a duplicative layer of barriers on top of the existing federal REMS framework for mifepristone.

### **Methotrexate: The Collateral Damage of Drug Reclassification**

When states use broad "abortion-inducing" classifications to restrict mifepristone and misoprostol, methotrexate risks being swept in by the same logic. South Carolina's HB 4760 illustrates this danger directly, explicitly listing methotrexate alongside mifepristone and misoprostol as an "abortion-inducing drug" subject to restriction.<sup>22</sup> While methotrexate is an abortion drug insofar as it terminates an ongoing pregnancy, it is exclusively used to end ectopic pregnancies which are both not viable and life threatening to the pregnant person.

### **Methotrexate Access after Dobbs**

Following Dobbs, physicians who commonly prescribe methotrexate, such as rheumatologists, feared that abortion restrictions would alter their clinical practice, expose them to legal liability,

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<sup>18</sup> [Impact of Dobbs on Evaluation and Treatment of Ectopic Pregnancy: National Survey of Emergency Physicians - PubMed](#)

<sup>19</sup> [Delayed and Denied: - How Florida's Six-Week Abortion Ban Criminalizes Medical Care](#)

<sup>20</sup> [In new complaint, Texas women say delayed care due to abortion laws endangered their fertility](#)

<sup>21</sup> [2025-2026 Bill 4760: Abortion-Inducing Drugs - South Carolina Legislature Online](#)

<sup>22</sup> [2025-2026 Bill 4760: Abortion-Inducing Drugs - South Carolina Legislature Online](#)

and compromise patient care.<sup>23</sup> These concerns extend to patients as well: those taking methotrexate who become pregnant may be unable to access abortion care, and the possibility of pregnancy may itself become a barrier to being prescribed the medication at all.<sup>24</sup> A recent survey of U.S.-based rheumatologists found that those practicing in abortion-restrictive states were more likely to report having changed, or planning to change, their methotrexate prescribing practices.<sup>25</sup> Any further efforts to restrict methotrexate access, like S.C. H. 4760, stands to only worsen access to this life saving medication for patients with a wide number of diseases.

In response to possible “chilling effects” on methotrexate prescribing already occurring as a result of the *Dobbs* decision and reports of patients being denied methotrexate due to its potential to terminate pregnancies, the U.S. Department of Health and Human Services (HHS) issued guidance<sup>26</sup> warning pharmacies that refusing to fill methotrexate for autoimmune diseases, such as rheumatoid arthritis, may violate federal civil rights laws under Section 1557 of the Affordable Care Act (ACA). As a result, pharmacists are caught in a “regulatory trap” between state abortion restrictions or bans and federal non-discrimination mandates.

## LEGISLATIVE LANDSCAPE

### Enacted Legislation

Louisiana (Act 246: Effective October 2024):<sup>27</sup> Louisiana became the first state to reclassify both mifepristone and misoprostol as Schedule IV controlled substances. Despite the explicit exemption shielding pregnant people from liability, the law altered the clinical landscape for emergency physicians, who routinely use misoprostol for miscarriage management, or obstetricians who use it for cervical ripening and postpartum hemorrhage, all time-sensitive indications where access delays can be life-threatening.<sup>28</sup>

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<sup>23</sup> [Overturning Roe v. Wade: Toppling the Practice of Rheumatology - PubMed](#)

<sup>24</sup> [The overturn of Roe v. Wade beyond abortion: a snapshot of methotrexate accessibility for people with rheumatic and musculoskeletal diseases-a mixed methods study using Twitter data - PubMed](#)

<sup>25</sup> [The impact of US abortion policy on rheumatology clinical practice: a cross-sectional survey of rheumatologists - PubMed](#)

<sup>26</sup> [Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services](#)

<sup>27</sup> [ACT No. 246](#)

<sup>28</sup> [Evaluating the Impact of Act 246 of the 2024 Louisiana Legislative Session: The Classification of Misoprostol and Mifepristone a](#)

Its requirements include:

**Specific Storage:** Medications must be stored in locked automated dispensing cabinets (such as Omnicell units).

**Prescription Drug Monitoring Program (PDMP) Reporting:** Every prescription must be reported to the state’s Prescription Monitoring Program, a surveillance system designed for drugs with addiction and diversion potential (these medications have no abuse profile).

**Mandatory Diagnosis Codes:** Prescribers must include a diagnosis code verifying a “non-abortion” indication—a task that is completely performative since abortion is completely banned in the state.

## Pending Legislation

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Mississippi (HB 1613: In Conference, March 2026):<sup>29</sup> This bill takes a drug trafficking approach rather than a straightforward Schedule IV reclassification. Under an amended version of HB 1613, anyone who is found to have prescribed or distributed mifepristone and misoprostol illegally can be charged criminally and found liable for civil penalties. This would include physicians, providers or community members who assist a patient to a medication abortion.

Missouri (HB 2160: Read Second Time, January 2026):<sup>30</sup> This bill reclassifies mifepristone as a Schedule IV controlled substance, placing it under the same regulatory oversight as narcotics and requiring tracking via the state’s Prescription Drug Monitoring Program (PDMP). Notably, the bill also establishes the offense of "coerced criminal abortion by means of fraud," specifically targeting the distribution of abortion-inducing drugs to a pregnant person without their knowledge or consent. The bill includes felony penalties for illicit distribution. There is no explicit exemption for the pregnant person.

South Carolina (H. 4760: Engrossed February 2026):<sup>31</sup> This bill follows the Louisiana model, classifying mifepristone and misoprostol as Schedule IV controlled substances, and notably extends that classification to methotrexate as well. The bill adds felony penalties of up to five years for distribution without a valid prescription. It also establishes the offense of "coerced criminal abortion by means of fraud," specifically targeting the distribution of abortion-inducing drugs to a pregnant person without their knowledge or consent. The pregnant person is explicitly exempted from prosecution, but the law does not reduce the chilling effect on anyone facilitating an abortion from providers to community organizations.

South Carolina (H. 4653<sup>32</sup> and S. 776<sup>33</sup>): Introduced January 2026, Status Pending): These bills classify mifepristone and misoprostol as Schedule IV controlled substances. Violation is a misdemeanor punishable by civil penalties and up to three years of imprisonment. There is no explicit exemption for the pregnant person. The bills were assigned to committees.

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<sup>29</sup> [HB1613 \(As Passed the House\) - 2026 Regular Session](#)

<sup>30</sup> [HB 2160](#)

<sup>31</sup> [2025-2026 Bill 4760: Abortion-Inducing Drugs - South Carolina Legislature Online](#)

<sup>32</sup> [2025-2026 Bill 4653: Controlled Substances - South Carolina Legislature Online](#)

<sup>33</sup> [2025-2026 Bill 776: Abortifacients - South Carolina Legislature Online](#)

South Carolina (S. 1095: Introduced April 2026, Status Pending):<sup>34</sup> This bill classifies mifepristone, misoprostol and methotrexate as Schedule IV controlled substances. The punishment for violations is less harsh than SC H 4760, imposing civil penalties and up to five years of imprisonment. This bill removes established protections and explicitly imposes criminal and civil penalties on the pregnant person for their own use of abortion medication. It also establishes the offense of "coerced criminal abortion by means of fraud," just like South Carolina's H. 4760. This bill would have catastrophic consequences on patient care, imposing criminal and civil penalties for providers, pregnant people, helpers, and abortion funds. The bill has not yet been assigned to a committee.

Kentucky (HB 646: Introduced February 2026, Status Pending):<sup>35</sup> This bill would classify mifepristone, misoprostol, and methotrexate as Schedule IV controlled substances, making distribution a felony with a mandatory prison term. The bill also opens civil legal action for anyone harmed by taking the drugs, allowing lawsuits against distributors, prescribers, and manufacturers. Like South Carolina's H. 4760 bill, it includes a carve-out explicitly exempting pregnant women from prosecution for personal possession, but imposes significant criminal and civil liability on providers and anyone involved in the supply chain, including criminalizing the "marketing" of abortion pills.

Iowa (SF 2155: Introduced January 2026, Status Pending):<sup>36</sup> This bill would classify mifepristone, misoprostol, and methotrexate as Schedule III controlled substances. Manufacturing, distributing, or dispensing these medications is a class C felony. There is no explicit exception for the pregnant person. This bill was assigned to the Senate Committee on Judiciary.

## **Failed Legislation**

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Texas (HB 818 / HB 1339 / HB 1636: 2025 Legislative Session, Did not advance prior to end of the session):<sup>37</sup> Texas legislators introduced three separate bills in the 2025 legislative session seeking to reclassify mifepristone and misoprostol as Schedule IV controlled substances. All three follow the Louisiana model, imposing controlled substance storage, PMP reporting, and prescribing documentation requirements. None of the three bills advanced, but the sponsors are expected to propose the bills again in the next session.

Missouri (HB 1367: 2025 Legislative Session, Did not advance prior to end of the session):<sup>38</sup> This bill would have classified mifepristone as a Schedule IV controlled substance and created the offense of "coerced criminal abortion by means of fraud," specifically targeting the distribution of abortion-inducing drugs to a pregnant person without their knowledge or consent. There was no explicit exemption for the pregnant person. This bill did not advance, but an identical bill was introduced during the 2026 Legislative Session (HB 2160).

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<sup>34</sup> [2025-2026 Bill 1095: Prohibit Abortions - South Carolina Legislature Online](#)

<sup>35</sup> [26RS HB 646](#)

<sup>36</sup> [Senate File 2155 - Introduced](#)

<sup>37</sup> [89\(R\) HB 818 - Introduced version - Bill Text](#)

<sup>38</sup> [HOUSE BILL NO. 1367](#)

Kentucky (HB 316: 2025 Legislative Session, Did not advance prior to end of the session):<sup>39</sup>This bill would have classified mifepristone, misoprostol, and methotrexate as Schedule IV controlled substances. The bill imposed harsher criminal and civil penalties on foreign senders, targeting out-of-state shield providers. There was no explicit exemption for the pregnant person. This bill did not advance, but Kentucky introduced a similar bill during the 2026 Legislative Session (HB 646).

## RECOMMENDATIONS

The legislative landscape described in this brief reflects a rapid and coordinated effort to restrict access to mifepristone, misoprostol, and methotrexate at the state level, through controlled substance reclassification, altering liability frameworks, mandatory reporting requirements, and the reversal of federal dispensing reforms. These mechanisms have produced documented harm to patients and clinicians when they have been implemented. The following recommendations are grounded in the clinical evidence, the public health data generated by the NOHD's September 2025 report and the established standards of major medical organizations.

### Cease Further Reclassification

No states should reclassify mifepristone, misoprostol, or methotrexate as controlled dangerous substances. The Schedule IV designation exists for medications with recognized potential for dependence or abuse, criteria that mifepristone, misoprostol, and methotrexate do not meet. The American College of Medical Toxicology has formally affirmed that reclassifying these drugs as controlled dangerous substances is clinically unjustified and sets a dangerous precedent of scheduling medications on political rather than pharmacological grounds.<sup>40</sup> New restrictions enacted in Louisiana (specifically locking dispensing cabinets) have been directly linked to clinical harm. States considering similar legislation should treat Louisiana not as a model, but as a warning.

### Implement Mandatory Impact Studies and Act on the Results

Legislatures should require State Departments of Health to systematically collect and publish data on the public health consequences of existing restrictions. The NOHD September 2025 report provides a replicable model. Without comparable data in other states, the full scope of harm remains invisible to policymakers. Mandated reporting should cover maternal morbidity linked to medication delays, changes in emergency miscarriage management wait times, and the frequency of pharmacy-level denials for non-abortion indications.

### Repeal Existing Restrictions Due to Documented Harms

Legislatures should repeal restrictions that are already in effect and causing measurable patient harm. Louisiana's Act 246 is the clearest case: real-world evidence has documented delays in

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<sup>39</sup> [AN ACT relating to the protection of unborn children. 1 Be it enacted by the General Assembly of the Commonwealth of Kentucky: 2](#)

<sup>40</sup> ACMT Position Statement: Mifepristone and Misoprostol are Not "Controlled Dangerous Substances"

hemorrhage response, disruptions to miscarriage and ectopic pregnancy management, and barriers to care for patients with no connection to abortion services.

### **Protect Clinical Judgment**

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The common mechanism of harm is legal ambiguity that causes clinicians to withhold standard care rather than risk prosecution or civil suit. ACOG and Physicians for Human Rights have documented that this chilling effect operates independently of whether a violation has actually occurred.<sup>41</sup> Legislation must include explicit safe harbor provisions protecting the use of these medications for any bona fide medical indication as determined by a licensed clinician, without exposure to lawsuits from private individuals, wrongful death suits, or civil liability. Without such protections, even well-intentioned “non-abortion” exemptions will fail to restore clinical confidence, as the Louisiana experience has shown.

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The **Advancing Impact on Maternal and Reproductive Health (AIM) Lab** at the Brown University School of Public Health is an interdisciplinary research hub dedicated to addressing the U.S. reproductive and maternal health crisis through rigorous evidence-based analysis and policy translation.

Led by experts in health law, emergency medicine, and national policy, the Lab focuses on high-stakes issues in a post-Dobbs landscape. By employing a harm reduction approach to protecting women’s health and safety, including ensuring access to emergency obstetric care in states with restrictive abortion policies, expanding contraceptive access and choice, advocacy for women experiencing intimate partner violence, and promoting evidence-based clinical guidelines and policies for perinatal substance use. By bridging the gap between public health, law, and social policy, the AIM Lab aims to serve as a national leader in generating nonpartisan data and tools that guide equitable healthcare delivery and influence state and federal policy decisions.

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<sup>41</sup> [Early Pregnancy Loss | ACOG](#)