



# ACT 246: MIFEPRISTONE & MISOPROSTOL AS CONTROLLED SUBSTANCES

Physician and Pharmacist Learning Session







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# DISCLAIMER

- This webinar is intended to provide an overview of Act 246 and share information on state policy changes that will impact the clinical practices of health care professionals in Louisiana.
- It will not be a discussion of any personal or political values, opinions, or beliefs related to Act 246 or any topic.

# LEARNING OBJECTIVES

## OBJECTIVE #1

Inform physicians and pharmacists about state changes made by Act 246 and subsequent guidance and information issued by LA Board of Pharmacy and LDH.

## OBJECTIVE #2

Prepare physicians and pharmacists for changes in policy and procedure for prescribing mifepristone and misoprostol for medically necessary and legal uses under Act 246.

## OBJECTIVE #3

Share best practices for prescribers and pharmacists to mitigate barriers to patient access to mifepristone and misoprostol for medically necessary and legal use.



# PANELISTS

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- Louisiana Emergency Physician

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## **Jane Martin, MD**

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- Public Policy Chair, Louisiana Society of Health-System Pharmacists

# ACT 246 OF THE 2024 LOUISIANA LEGISLATIVE SESSION

- Takes effect October 1, 2024
- Creates the crime of coerced criminal abortion
  - Use of abortion inducing drug on a pregnant woman without her consent
  - Penalties of 5-10 years imprisonment and \$10K-\$75K fine
- Adds mifepristone and misoprostol to the state's Schedule IV controlled substances list
  - Exception for a pregnant woman to possess mifepristone or misoprostol for her own consumption



# ACT 246 REQUIRED NOTIFICATIONS

## ACT 246 DIRECTS:

Louisiana Department of Health to notify all healthcare practitioners and providers in Louisiana about Act 246 and that mifepristone and misoprostol may be prescribed and administered in accordance with R.S. 14:87.9(C)(6).

**LDH GUIDANCE**

Louisiana Board of Pharmacy to notify all pharmacists of Act 246 and that lawful prescriptions for mifepristone and misoprostol may be filled in accordance with R.S. 14:87.9(C)(6).

**LA BOARD OF PHARMACY BULLETIN**



# **R.S. 14:87.9(C)(6)**

Any act by a licensed pharmacist or pharmacy related to filling a prescription for a drug, medicine, or other substance prescribed for a bona fide medical reason shall not subject the pharmacist or the pharmacy to the criminal consequences of this Section. A diagnosis or a diagnosis code shall be written on the prescription by the prescriber indicating that the drug, medicine, or other substance is intended for a purpose other than to cause an abortion in violation of this Section.



# CONTROLLED SUBSTANCE REVIEW







## WE ARE IN THIS TOGETHER

The practitioner is responsible for the proper prescribing **and dispensing of controlled substances**, but a corresponding responsibility rests with the pharmacist who fills the prescription.



# WE ARE IN THIS TOGETHER

... a prescription that is not issued for a legitimate medical purpose in the usual course of professional treatment... is not a prescription...

The person knowingly filling such... prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances. [21 U.S.C. 841\(a\)\(1\)](#) and [21 CFR 1306.04\(a\)](#).



# TITLE 40 § 964.

## COMPOSITION OF SCHEDULES...

### SCHEDULE IV

#### A. NARCOTICS

Difenoxin 1 mg & 25 mcg Atropine/tab

#### B. DEPRESSANTS

Alprazolam, Phenobarbital

#### D. STIMULANTS

Phentermine, Sibutramine

#### E. OTHER SUBSTANCES

Pentazocine, Butorphanol, Eluxadoline

#### F. MIFEPRISTONE AND MISOPROSTOL

\*It shall not be a violation of this Subsection for a pregnant woman to possess mifepristone or misoprostol for her own consumption.



# MIFEPRISTONE (MIFEPREX, KORLYM)

- Synthetic progestin and glucocorticoid receptor antagonist
- Utilized in OB/GYN capacity but also for treatment of hyperglycemia and Cushing syndrome
- Existing mifepristone Risk Evaluation Mitigation Strategy (REMS) remains unchanged
- Therapeutic uses include cervical canal dilation, labor induction, treatment of spontaneous, missed, incomplete and inevitable abortion, and (where legal) elective termination of pregnancy when utilized in combination with misoprostol, treatment of Cushing Syndrome and hyperglycemia



# MISOPROSTOL (CYTOTEC)

- Synthetic prostaglandin E1 analog
- Binds to parietal cells in stomach – inhibit gastric acid secretion
- Binds to smooth muscle cells in uterus – promote labor/cervical ripening for delivery
- FDA approved for prevention and treatment of gastric ulcers induced by NSAIDs



# MISOPROSTOL USES

## OUTPATIENT

- Management of miscarriage/spontaneous abortion
- Prevention and treatment of NSAID-induced gastric
- Cervical preparation prior to dilational procedures (Hysteroscopy, D&C for indicated purposes)
- Cervical preparation for procedures navigating through the cervix to access the endometrial cavity (IUD insertion, endometrial biopsy, collecting ECC during colposcopy)



## SELECTED NON-PREGNANCY RELATED MISO USES

IUD

Z30.430 Insertion of IUD  
Z30.432 Removal of IUD

Colposcopy

Z12 Screening for cervical cancer  
N88.2: Cervical stenosis/cervical os stenosis

Hysteroscopy\*

N88.2: Cervical stenosis/cervical os stenosis

Endometrial Biopsy\*

N88.2: Cervical stenosis/cervical os stenosis



# DIAGNOSIS CODES

**002.1:** Missed abortion

**003.4:** Incomplete abortion

**003.9:** Spontaneous abortion

**003.9:** Miscarriage

**072.0:** Retained products of conception, postpartum

**002.1:** Retained products of pregnancy, early pregnancy

**003.4:** Retained products of conception after miscarriage

**072.1:** Postpartum hemorrhage

**062.2:** Uterine atony

**N88.2:** Cervical stenosis/cervical os stenosis



# MISOPROSTOL USES

## INPATIENT

- Induction of labor
- Cervical preparation prior to dilational procedures (Hysteroscopy, D&C for indicated purposes)
- Management of postpartum hemorrhage

Drug*	Dose and Route	Frequency	Contraindications
Oxytocin	IV: 10–40 units per 500–1,000 mL as continuous infusion or IM: 10 units	Continuous	Rare, hypersensitivity to medication
Methylergonovine	IM: 0.2 mg	Every 2–4 h	Hypertension, preeclampsia, cardiovascular disease, hypersensitivity to drug
15-methyl PGF <sub>2α</sub>	IM: 0.25 mg Intramyometrial: 0.25 mg	Every 15–90 min, eight doses maximum	Asthma. Relative contraindication for hypertension, active hepatic, pulmonary, or cardiac disease
Misoprostol	600–1,000 micrograms oral, sublingual, or rectal	One time	Rare, hypersensitivity to medication or to prostaglandins





<b>MISO INDICATIONS &amp; USES</b>	<b>DOSAGE</b>
NSAID-induced ulcers	200 mcg 4 X daily
Cervical ripening	25 mcg intravaginally every 3 - 6 hours
Miscarriage	800 mcg intravaginally, may repeat with mifepristone 200 mg orally, 1st day
Postpartum hemorrhage	600-1000 mcg orally, sublingually, rectally



# IMPLEMENTING ACT 246





# RELEVANT CONTROLLED SUBSTANCE REGULATIONS

## TELEHEALTH PROVIDERS

Need State License, DEA-Suffix or DEA

## LA PROVIDERS/RESIDENTS

Need LA License, DEA-Suffix or DEA, LA CDS

## APRN, PA

Need LA License, DEA-Suffix or DEA, LA CDS

## C-IV RX GUIDANCE

May be electronic, written, or oral

May have up to 5 refills, fillable within 6 months from DOI

Has no limits on quantity in Louisiana

Misoprostol or mifepristone must have ICD-10 or diagnosis



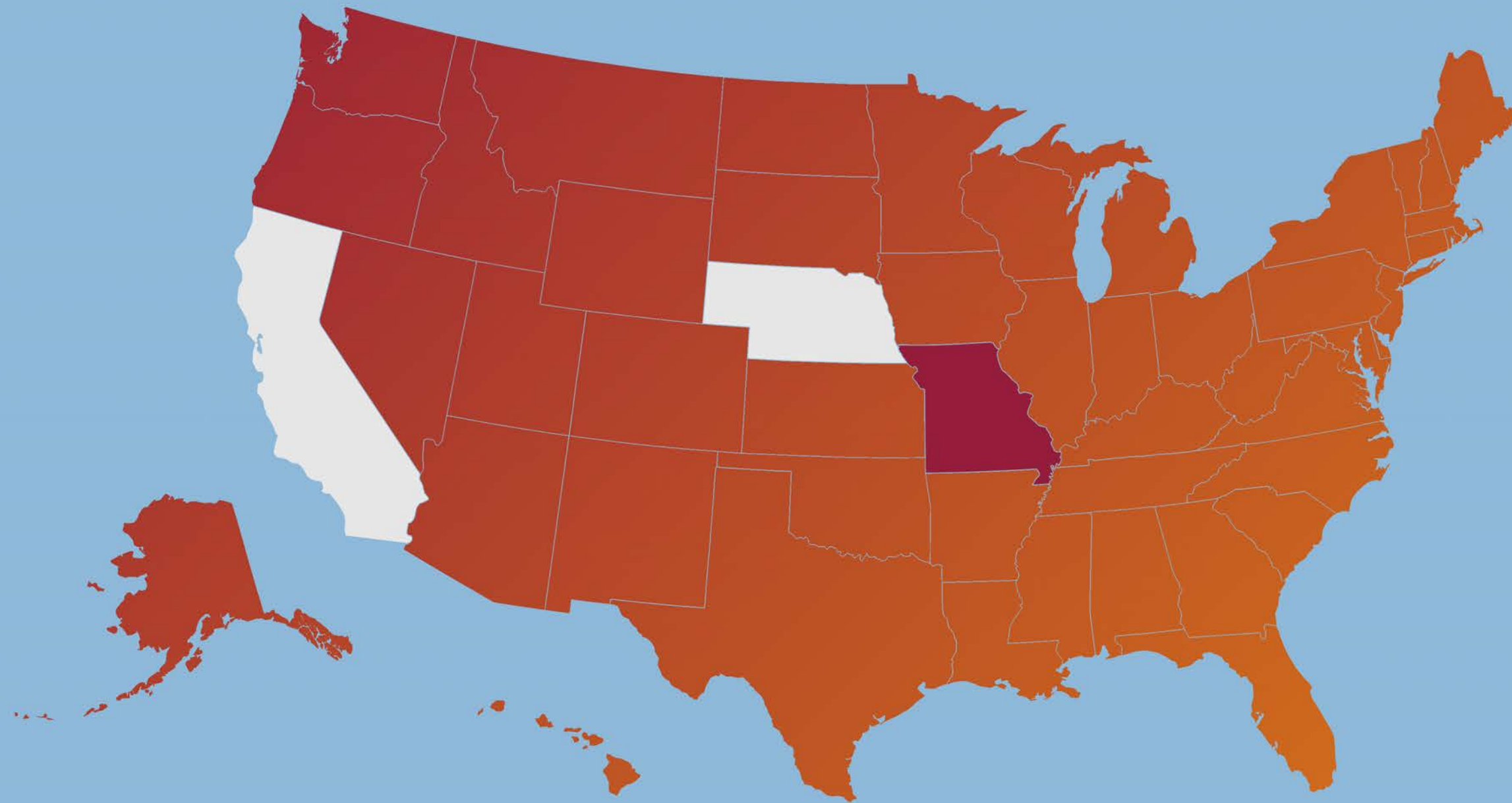
# RELEVANT CONTROLLED SUBSTANCE REGULATIONS

1. Physician note needed in the electronic health record to justify use
2. Must be stored in a “locked cabinet”
3. Routine maintenance of inventory
4. C-IV drugs that are lost, wasted\* or stolen must be documented on DEA Form 106

**\* Partially used vials or dosage packages with small amounts remaining after use do not count as waste**



# PRESCRIPTION MONITORING PROGRAM



● STATE PARTICIPANTS ● CITIES/COUNTIES PARTICIPANTS ● PROSPECTIVE PARTICIPANTS

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY



# THE FOLLOWING DATA ARE CONSISTENTLY COLLECTED

- ✓ **Pharmacy** (Name, DEA, CDS, NPI, Address, Phone)
- ✓ **Prescriber** (Name, DEA, CDS, NPI, Address, Phone)
- ✓ **Patient** (Name, DOB, Gender, Address)
- ✓ **Dates** the Rx was written and filled
- ✓ **NDC Number** (Name, Dosage, Dosage Form, Package)
- ✓ **Route, Quantity dispensed & Number of refills**
- ❗ Louisiana adds **Method of Payment** (not rare)



# LOUISIANA PMP

- Dispensers are required to input all C II-V Rx, All Tx Cannabis Requests, All Drugs of Concern
- Prescribers are required to review a patient specific PMP report for all the above, when Tx exceeds 90 days, as well prior to prescribing. The DEA prefers a review prior to all Rx.
- Dispensers are directed to review a patient specific PMP report for all the above as well prior to dispensing.



# AVAILABLE REPORTS FROM LA PMP

**Basic Report with list of prescriptions by prescriber per date of issue**  
**PMP Advisory Board by Direct Query** *Per Period*

 Drugs Prescribed or Dispensed / State, Parish, Provider Group

**Licensing Boards\* by Direct Query** *Per Complaint or Issue*

 Rx per Patient, MME-related, @ Risk Rx, Comparisons

**Law Enforcement, Courts by Indirect Query** *Per Subpoena, Request*

 For Suspected Diversion or Criminal Trafficking

**Substant Use Counselors, Parole Officers by Indirect Query**

 For Client or Charge Compliance with Drug-Related Activities

\* Louisiana Medicaid, Louisiana State Legislative Auditor, LDH



# ACT 246 - LA BOARD OF PHARMACY BULLETIN

- Inventory misoprostol and mifepristone on Oct 1
- Prescriptions filled need diagnosis code
- Report to the PMP as with all Controlled Dangerous Substances (CDS)
- Prescriptions need to comply with CDS regulations

**FULL LOUISIANA BOARD OF PHARMACY BULLETIN**



# ACT 246 - LA BOARD OF PHARMACY BULLETIN

- Pursuant to hospital licensing rules, all scheduled drugs should be compounded, packaged, dispensed, and securely stored (in a locked/secured cabinet, compartment, or other system) in accordance with the hospital's current policies and procedures.
- A hospital may include mife/miso in a **secured automated medication dispensing/delivery system**, such as the Pyxis system.
- Further, a hospital may authorize certain scheduled drugs to be included in a locked or **secured area of an obstetric hemorrhage cart or "crash cart"**.
- Such authorization should be **approved by the hospital's Chief Medical Officer and its Director of Pharmacy**.
- Additionally, such approval and process should be included in the **hospital's pharmacy policy and procedures** manual.

[FULL LDH GUIDANCE](#)



# ADDRESSING BARRIERS TO MISOPROSTOL IN INPATIENT SETTINGS

- **Hospitals should formulate a process that allows misoprostol to be immediately available** for all patients receiving care in the following units: **ED, OBED, antepartum, labor & delivery, postpartum.**
- **This may vary based on location of medication storage unit in relation to patient care areas, use of postpartum hemorrhage risk assessment tools, and nursing availability** to perform mandatory medication access and return process.
- **Multidisciplinary planning** may include participation from: physicians, nurses, hospital administration, inpatient pharmacy, compliance, quality improvement.



# ADDRESSING BARRIERS IN OUTPATIENT SETTINGS

- Multiple diagnosis codes – many that are appropriate – appropriate documentation in outpatient notes also
- Missing diagnosis codes on Rx
- Pharmacy delays/problems filling prescription



# NOHD REPORTING FORM

Home » Health Department » Sexual and Reproductive Health » Patient and Provider Reporting Form

## HEALTH DEPARTMENT

Health Department  
Learning is Fun  
About  
Calendar  
Behavioral Health  
Climate & Health  
Chronic Disease  
Community Health Improvement  
Coronavirus  
Data and Publications  
Domestic Violence and Sexual Assault Program  
Environmental Health Initiatives  
Family Connects  
Food Security & Nutrition  
Health Care Access  
Health Care for the Homeless  
Health Equity  
Health Policy  
Healthy Start  
Homelessness  
Injury Prevention and Transportation Safety  
Public Health Emergencies  
Ryan White HIV/AIDS Program  
Sexual and Reproductive Health  
Got It\* On NOLA  
Patient and Provider Reporting Form  
Smoke-Free Ordinance  
Sound Check  
Violence Prevention  
Women, Infants, and Children (WIC)  
Working With Us

### Misoprostol and Mifepristone Access - Patient and Provider Reporting Form

All feedback is completely anonymous and confidential with the purpose of better understanding the Impacts of [ACT 246](#), which placed Misoprostol and Mifepristone on Louisiana's Schedule IV Controlled Substances List. The form should be used to report challenges to accessing Misoprostol or Mifepristone for legal, medically necessary use through a health care provider and/or pharmacist in Louisiana.

Please do not include protected health information unless you are a patient and willing to disclose.

1. What is your zip code of residence? \*

2. Please select the option that best describes you: \*

Medical Provider  
 Pharmacist  
 Community Member  
 Other

If you selected Other, please describe:

3. When did the issue occur?

 Today

4. Please describe the issue in as much detail as possible: \*

5. Where did the issue occur? Please list the location or workplace address:

6. Any other concerns raised by this incident?

7. Would you like us to follow-up with you?

Follow-up is completely optional at your discretion. If yes, please share your name and preferred contact method.

Submit

\*Report notifications will be sent directly to designated NOHD team

*This is a preview of the form. The form is not currently posted on the NOHD website, but can be found here when it is ready to go live.*



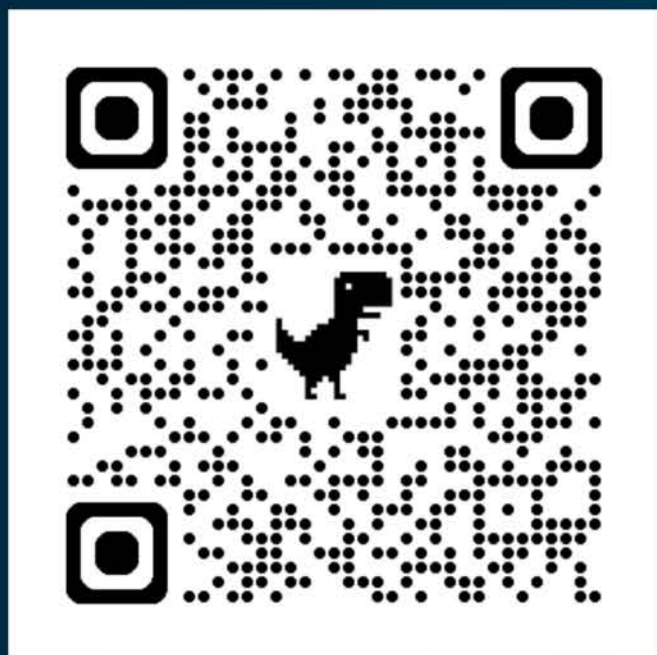
**Q&A**





# THANK YOU

Please take a moment to complete the evaluation.



[WWW.SURVEYMONKEY.COM/R/ACT24](https://www.surveymonkey.com/r/act24)

