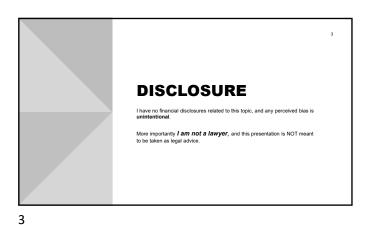
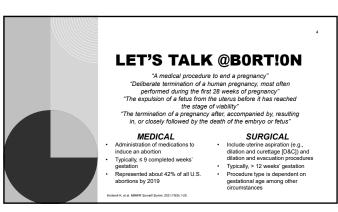


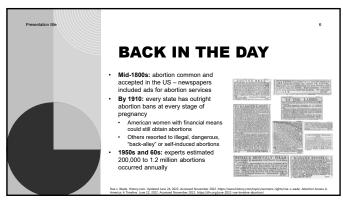
LEARNING OBJECTIVES ✓ REVIEW the original Roe v. Wade ruling and how it impacted healthcare in the United States ✓ DISCUSS Dobbs v. Jackson Women's Health Organization and its impact on Roe v. Wade ✓ IDENTIFY the implications of these Supreme Court rulings on pharmacy practice

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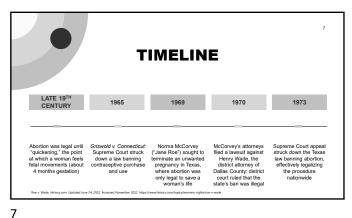


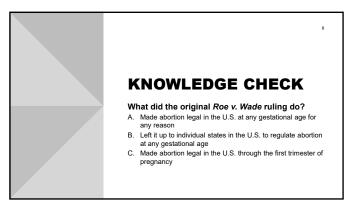




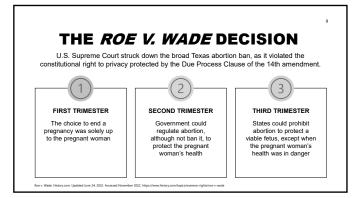


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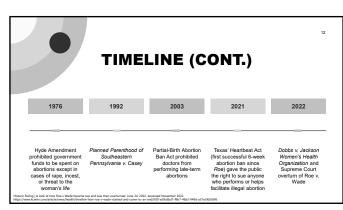


AFFIRMING THE ROE RULING • In 1992, Planned Parenthood of Southeastern Pennsylvania v. Casey reached the Supreme Court Litigation against Pennsylvania's Abortion Control Act, the most restrictive abortion provisions at the time The ruling cited "stare decisis" (adhering to precedent) in upholding the *Roe* verdict But, upheld all Pennsylvania abortion requirements except spousal notification Changed the trimester framework, allowing states to regulate pre-viability abortions provided a "substantial obstacle" or "undue burden" is not added While Casey reaffirmed the right to an abortion, it also provided states more leeway in passing restrictive laws

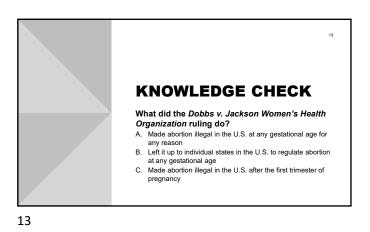
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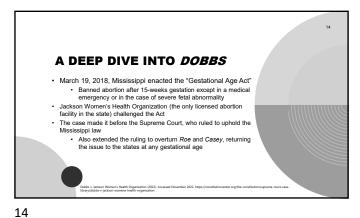
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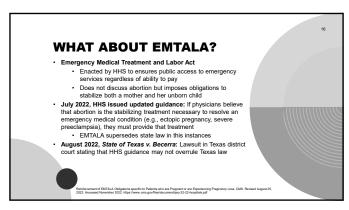


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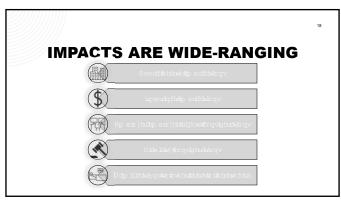


Expanded access: protected by state statutes or constitutions, and other laws and policies have created additional access. Protected: protected by state statutes or uprotected: may remain accessible, but uprotected by state and territory law Hostile: have expressed a desire to prohibit entirely; vulnerable to revival of old bans or enactment of new ones, and no existing legal protections lilegal: ban abortion entirely and enforce those bans through criminal penalties

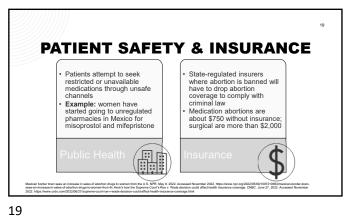


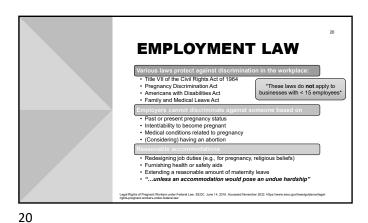
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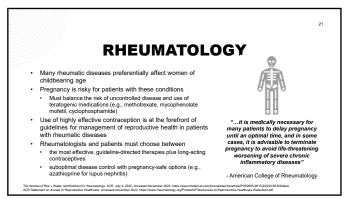


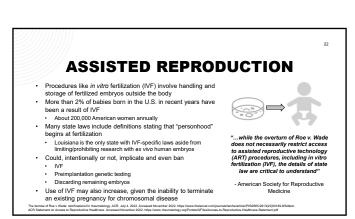


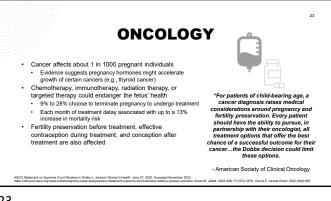
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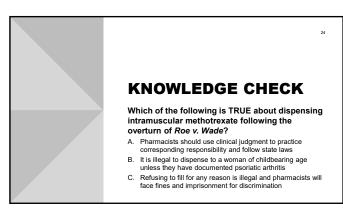


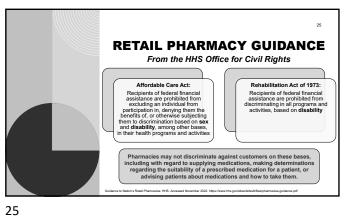












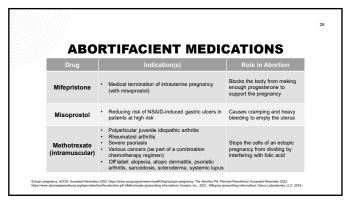
WHAT-IF... A recently hired technician informs you on his first day that he refuses to fill prescriptions for or sell contraceptives, emergency contraception, or abortifacient medications based on his religious beliefs. Consider the following: Can you provide reasonable accommodations? Can you always schedule another technician/RPh with him, or would this pose undue hardship on the pharmacy? This may violate HHS guidance about discrimination based on sex. How will you ensure this employee does not make patients feel discriminated against? Is your patient population likely to be affected? Are you located, for example, near a large university with many women of childbearing potential? Does your pharmacy serve only senior citizens in assisted living facilities?

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WATCH YOUR LANGUAGE Abortifacient: Teratogenic: capable of interfering with used to terminate a the development of a pregnancy fetus, causing birth defects

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MIFEPRISTONE REMS Healthcare providers who prescribe mifepristone must: Review prescribing information and complete a Prescriber Agreement Form. Review the Patient Agreement Form with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone. Sign the Patient Agreement Form and obtain the Patient's signature on the form. Provide the patient with a copy of the Patient Agreement Form and Medication Guide. Place the signed Patient Agreement Form in the patient's medical record. Flace of the serial number from each package of mifepristone in each patient's record.

Report the serial number from each package of mifepristone in each patient's record.

Report any deaths to the Mifepristone Sponsor that provided the mifepristone, identifying the patient by a non-identifiable reference and the serial number from each package of mifepristone. Patients who are prescribed mifepristone must sign a Patient Agreement Form stating that the patient has: Received, read and been provided a copy of the Patient Agreement Form.

Received counseling from the prescriber regarding the risk of serious complications associated with mifepristone.

AN EVOLVING LEGAL LANDSCAPE

- The Court's decision in *Dobbs* complicates the legal landscape surrounding medication abortion
- · Some state provisions that limit these drugs' availability aim to restrict access beyond what federal law would otherwise permit
 - In 33 states, only a licensed physician may prescribe medication abortion drugs
 - 19 states require the physician to be in the physical presence of the patient or place restrictions on the use of telehealth
- · Questions may arise about federal preemption

FEDERAL PREEMPTION

- When a validly enacted federal law supersedes an inconsistent state law
- Occurs when it is "impossible for a private party to comply with both state and federal requirements" or if the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"
- A recent example: Zogenix, Inc. v. Patrick (2014)
- A Massachusetts order generally barred prescribing and dispensing an opioid medication based on concerns of diversion, overdose, and abuse

 The state agued that the order was a permissible exercise of its traditional state police powers
- The court concluded that the ban on the drug was an "obstruction" that undermined the FDA's authority to make "drugs available to promote and protect the public health"
- The state instead established requirements for prescribers to take certain actions when prescribing the opioid and for pharmacies to take specified steps to prevent diversion

ion Abortion: A Changing Legal Landscape. CRS. October 5, 2022. Accessed November 2022. https://crsreports.congress.gov/product/pdf/LSBLSB10708

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FEDERAL PREEMPTION AND DOBBS

- Dobbs returned the authority to regulate abortion "to the people and their elected representat Additional state abortion restrictions are likely, and Congress may consider federal legislation

Proposed Federal Legislation What It Means Would require an abortion provider to be "physically present at the location" of a medication abortion; a provider who violates would be fined $\leq $1,000$ or imprisoned for ≤ 2 years, or both Teleabortion Prevention Act of 2021 Women's Health Protection Act of 2021 Would guarantee health care providers a statutory right to provide abortion services and preempt any state law that would limit or restrict that right Would codify the "essential holdings" of Roe and Casey and provide that a state may not impose an undue burden on a woman's ability to have an abortion before fetal viability, would allow abortion restrictions under the standard established in Casey Reproductive Choice Act

CORRESPONDING RESPONSIBILITY

- Not new pharmacists have always been the gatekeepers
- If pharmacists fill orders they suspect are not legitimate, criminal and regulatory charges possible
- Large retail chains have circulated memos regarding abortifacient medications specifically
- Reviews diagnosis codes that are deemed acceptable for dispensation
- "When dispensing a prescription for misoprostol or methodrexate to women of child-bearing potential in states that prohibit dispensing medications for the purpose of inducing abortion, pharmacists should validate that the intended indication is not to terminate a pregnancy."
- Includes not filling the prescription without a diagnosis code, until they confirm it with the prescribing doctor; if they find abortion is the intended use, they "must refuse to fill the prescription"

Pharmacies are also incorporating it into their DUR process or automatically rejecting the prescription until a pharmacist reviews it

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WHAT ABOUT HIPAA?

The short answer: Nothing changes. PHI—including information relating to abortion and other sexual and reproductive health care—will be kept private under HIPAA Privacy Rule.

The long answer: HIPAA Privacy Rule allows for PHI disclosure without an individual's authorization for purposes not related to healthcare in limited circumstances.

1) Disclosures Required by Law - when such disclosure is required by another

- law and the disclosure complies with the requirements of the other law
- Disclosures for Law Enforcement Purposes for law enforcement purposes "pursuant to process and as otherwise required by law," under certain conditions
- 3) Disclosures to Avert a Serious Threat to Health or Safety if the covered entity, in good faith, believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public, and the disclosure is to a person or persons who are reasonably able to prevent or lessen the threat

WHAT-IF... An individual goes to a hospital emergency department while experiencing complications related to a miscarriage during the tenth week of pregnancy. You work in a state where a 6-week abortion ban is in effect, and a provider suspects the individual of having taken medication to end their pregnancy.

- State law prohibits abortion after 6 weeks gestation but does not require the hospital to report individuals to law enforcement
- Where state law does not **expressly require** such reporting, the Privacy Rule would **not** permit a disclosure to law enforcement under the *Required by Law*
- Disclosure would be impermissible and constitute a breach of unsecured PHI

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WHAT-IF...

A law enforcement official comes to your pharmacy and requests records of all patients who have received both mifepristone and misoprostol.

- If the request is not accompanied by a court order or other mandate enforceable in a court of law, the Privacy Rule would **not** permit the pharmacy to disclose PHI in response to the request.

 Disclosure would be impermissible and constitute a breach of unsecured PHI

What if they have a court order requiring the pharmacy to produce PHI about a specific individual?

- Because a court order is enforceable in a court of law, the Privacy Rule would permit but not require the pharmacy to disclose the requested PHI
 Disclosure must only include the PHI expressly authorized by the court order

SUMMARY The reality: a great deal of **gray area** surrounds this topic and the situation is fluid Remain aware of your state's laws and regulations and your company's policies, and when in doubt, ask the prescriber for more information Consider how Supreme Court rulings may impact care in your patient population If you believe you may be in a situation you morally, ethically, or religiously object to, be up front with your employer about reasonable accommodations

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