Reproductive Health

California Hospital Association

Agenda

- ✓ Abortion Pre-*Dobbs*
- ✓ *Dobbs v. Jackson Women's Health Organization (2022)*
- ✓ Post-*Dobbs*
- ✓ State Abortion Bans
- ✓ State Abortion Protections
- ✓ Conscience Protection Laws
- ✓ EMTALA
- ✓ Does EMTALA preempt state law?
- ✓ Abortion Medication
- ✓ What does this mean for California Hospitals?!

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Abortion *Pre-Dobbs*

1847:

Formation of the American Medical Association.

AMA members launched a criminalization campaign against abortion and female abortion providers. State legislatures moved to ban abortion.

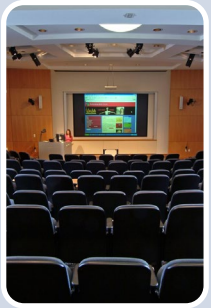
1880s: Abortion Criminalized.

By 1880, all states had laws to restrict abortion – with exception in some states if a doctor said the abortion was needed to save the life or health of the patient.

1930:

Deaths from Illegal, Unsafe Abortions.

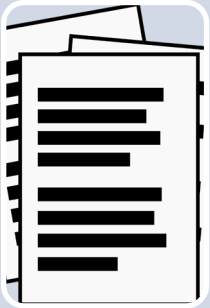
Criminalizing abortion send the practice underground, which resulted in a high death toll. Unsafe, illegal abortion was the cause of death for nearly 2,700 women in 1930.



1955:

Conference on Abortion Legalization.

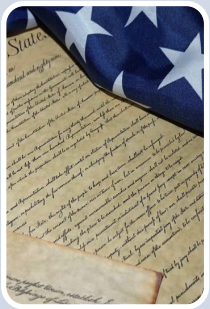
In response to increasingly alarming media coverage of unsafe, illegal abortions, Planned Parenthood held a first-of-its-kind conference on the issue of abortion. The doctors who attended the national conference called for abortion law reform.



Late 1960/Early 1970s:

Abortion Reform.

By the late 1960s, a nationwide effort was underway to reform abortion laws. By 1973, 4 states had repealed their abortion bans entirely, while 13 enacted reforms expanding exceptions.



1973:

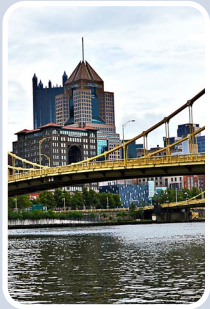
Roe v. Wade.

The U.S. Supreme Court recognized for the first time that the constitutional right to due process is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.

1976:

Hyde Amendment.

Prevents federal dollars from being used in government insurance programs like Medicaid for abortion services (except in instances of incest, rape, or life-threatening risk to the pregnant person).



1992:

Planned Parenthood of Southeastern Pennsylvania v. Casey.

Reaffirmed that the Constitution protects the right to abortion. Created "undue burden" framework under which laws restricting access to abortion would be judged.

2007:

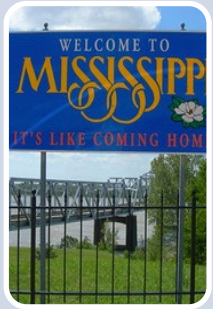
Gonzalez v. Carhart.

The U.S. Supreme Court upheld the first federal legislation to criminalize abortion, allowing Congress to ban 2nd-3rd trimester abortion procedures.

2016:

Whole Woman's Health v. Hellerstedt.

The U.S. Supreme Court ruled that two Texas abortion restrictions were unconstitutional because they would shut down most abortion providers in the state and impose an "undue burden" on access to abortion in Texas.



2018:

Mississippi passes 15-week abortion ban.

In March 2018, Mississippi enacted H.B. 1510, which bans abortion after 15 weeks of pregnancy.

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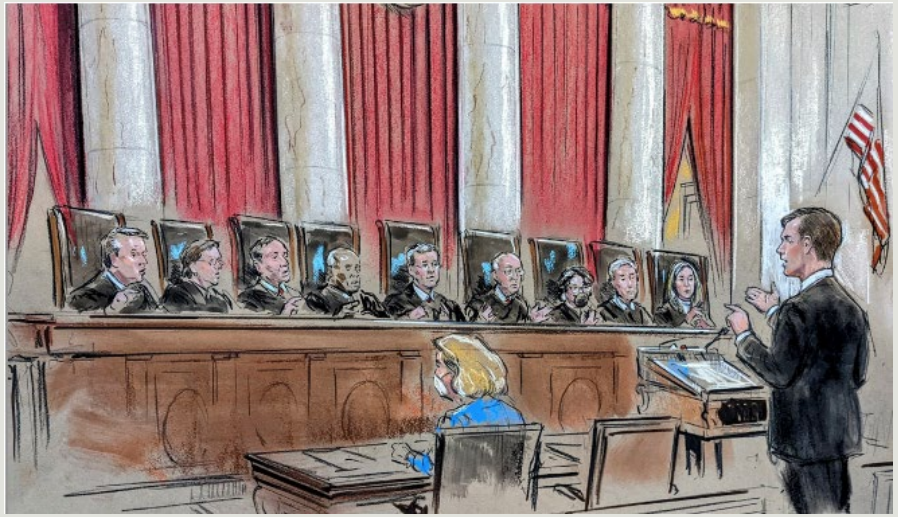
Dobbs v. Jackson Women's Health Organization (2022)



"We hold that Roe and Casey must be overruled. The Constitution makes no reference to abortion, and no such right is implicitly protected by any constitutional provision, including the one on which the defenders of Roe and Casey now chiefly rely—the Due Process Clause of the Fourteenth Amendment. That provision has been held to guarantee some rights that are not mentioned in the Constitution, but any such right must be 'deeply rooted in this Nation's history and tradition' and 'implicit in the concept of ordered liberty."

"The Court finds that the right to abortion is not deeply rooted in the Nation's history and tradition."

Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 142 S. Ct. 2228, 213 L. Ed. 2d 545 (2022)

No Federal Constitutional Right to Abortion

- On June 24, 2022, the U.S. Supreme Court overruled *Roe v. Wade* and *Planned Parenthood v. Casey*, holding that there is no constitutional right to abortion.
- Without a federal right to abortion access, state regulation of abortions is only limited by state constitutions.

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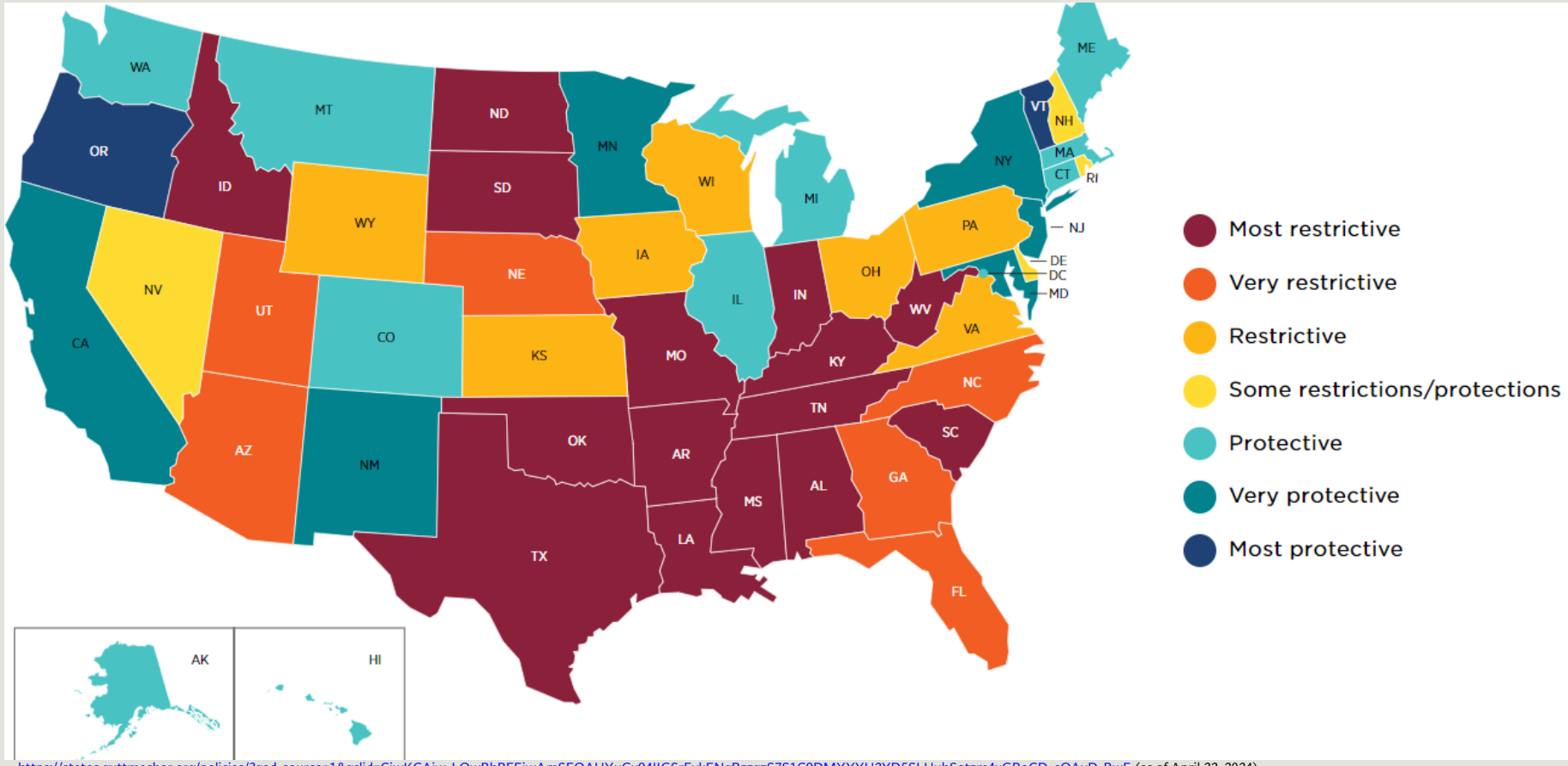
Post-*Dobbs*



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State Abortion Bans

Total Bans – 14 States

(AL, AR, ID, IN, KY, LA, MS, MO, ND, OK, SD, TN, TX, WV)

[with limited exceptions e.g. where "necessary in order to prevent a serious health risk to the unborn child's mother;" to "save the life of a pregnant woman in a medical emergency."]

Banned after ~6 weeks – (GA, SC)

Banned after 12 weeks – (NC, NE)

Banned after 15 weeks – (GA, MT, AZ*)

Banned after 18 weeks – (UT)

https://states.guttmacher.org/policies/?gad_source=1&gclid=CjwKCAjw_LOwBhBFEiwAmSEQAUYuGv94IlGSrFykENgRzzgzS7S1C9DMYYYU2YD5SLUuhSotzm4xGRoCD-cQAvD_BwE (as of April 22, 2024)

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State Abortion Protections

Protects Abortion in State Statute	State Constitutional Amendment - Voter Approved	Prohibits Certain Entities from Cooperating with Out-of-State Abortion-Related Investigations/Subpoenas
• CA, CO, HI, IL, MD, MA, MN, NJ, NM, NY, OR, VT, WA, DC	• CA, MI, VT, OH • [KS, KY]*	• CA, CO, CT, HI, IL, MA, NJ, NM, NY, WA, VT

Requires Private Insurance Coverage for Abortion Services	Permits Certain Non-Physician Advanced Practitioners to Perform Certain Abortion Services (NPs, Pas)	Protects Providers from Certain Penalties
• CA, CO, IL, ME, MD, NJ, NY, OR, VT, WA	• CA, CT, DE, HI, IL, ME, MD, MS, MT, NJ, NY, RI, VA, DC	• CA, CO, DE, IL, ME, MA, MN, NJ, NM, NY, OR, VT, WA, DC

Conscience Protection Laws

Federal Conscience Protection Laws:

- **Church Amendments – 42 USC 300a-7**: Consists of 5 conscience provisions generally providing that entities cannot discriminate against individuals or applicants based on a refusal to participate in an activity contrary to religious beliefs or moral convictions, including abortions or sterilization.
- **PHS Act – 42 USC 238N**: Prohibits federal, state and local governments receiving federal financial assistance from discriminating against entities that refuse to provide abortion training.
- **ACA Section 1303 - 42 USC 18023(d):** Prohibits health care providers that receive federal funding under the ACA or health plans created under the ACA from discriminating based on an entity or individual not providing assisted suicide or abortion. Includes: **"**Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law."
- **Federal 2024 Rule – Safeguarding the Rights of Conscience as Protected by Federal Statutes**: The rule "restores the longstanding process for handling conscience complaints," and "strengthens safeguards to protect against conscience and religious discrimination" against employees and health care clinicians as contemplated under federal law including the Church Amendments, ACA, etc..

State Conscience Protection Laws:

- Nearly every state has adopted one or more health care conscience laws that apply in the context of reproductive health services, including abortion, sterilization, contraception, and emergency contraception.

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EMTALA

EMTALA requires Medicare-participating hospitals with *dedicated emergency departments* to:

Screen – Provide a medical screening examination (MSE) to an individual who has come to a dedicated emergency department, seeking or in need of evaluation/treatment or, in certain circumstances has come to other parts of the hospital campus.

Stabilize – If an emergency medical condition (EMC) exists, provide stabilizing treatment within the hospital's capability and capacity

Transfer – If a hospital cannot stabilize the EMC, arrange for an appropriate transfer of the individual to another facility for stabilizing treatment

EMTALA

"Emergency Medical Condition"

- An individual has an emergency medical condition if the absence of immediate medical attention could reasonably be expected to result in: (i) placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; (ii) serious impairment to bodily functions; or (iii) serious dysfunction of any bodily organ or part. 42 USC 1395dd(e)(1)(A).

"To Stabilize"

- To stabilize means to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility. 42 USC 1395dd(e)(3)(A).

EMTALA Post-*Dobbs*

FOR IMMEDIATE RELEASE
July 11, 2022

Contact: HHS Press Office
202-690-6343
media@hhs.gov

Following President Biden's Executive Order to Protect Access to Reproductive Health Care, HHS Announces Guidance to Clarify that Emergency Medical Care Includes Abortion Services

Today, the U.S. Department of Health and Human Services (HHS) announced new guidance and communication to ensure all patients — including pregnant women and others experiencing pregnancy loss — have access to the full rights and protections for emergency medical care afforded under the law. This announcement follows President Biden's executive order on reproductive health issued Friday.

HHS, through the Centers for Medicare & Medicaid Services (CMS), issued clarifying guidance on the Emergency Medical Treatment and Active Labor Act (EMTALA) and reaffirmed that it protects providers when offering legally-mandated, life- or health-saving abortion services in emergency situations. In addition to the guidance, Secretary Xavier Becerra, in a letter to providers, made clear that this federal law preempts state law restricting access to abortion in emergency situations - PDF.

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Does EMTALA preempt state law?

Moyle v. U.S.

- United Stated sued Idaho arguing that Idaho's abortion ban violated the supremacy clause because EMTALA requires stabilizing care when a pregnant woman suffers an emergency medical condition (not only in life-threatening situations (e.g. Idaho's narrow abortion exception)).
- Idaho District Court enjoined Idaho's abortion to the extent it conflicted with EMTALA.
- Ninth Circuit denied a request to stay the District Court's decision.
- SCOTUS grants requests to stay the District Court's decision until it hears the case.
- Oral arguments on April 24, 2024.

Becerra v. Texas

- Texas sued HHS to enjoin enforcement of HHS guidance on EMTALA arguing that the guidance mandates providers to perform elective abortion in excess of HHS's authority.
- Texas District Court enjoined the guidance's interpretation of EMTALA within Texas and the 5th Circuit affirmed finding that EMTALA does not mandate abortion care nor does it preempt Texas law.
- On April 1, 2024, HHS submitted a petition for a writ of certiorari and request to be considered with the Idaho case.

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SCOTUS REVIEW: *Idaho v. US; Moyle v. US (2024)*

QUESTION PRESENTED

Whether the Emergency Medical Treatment and Labor Act, 42 U.S.C. 1395dd, preempts state law in the narrow but important circumstance where terminating a pregnancy is required to stabilize an emergency medical condition that would otherwise threaten serious harm to the pregnant woman's health but the State prohibits an emergency-room physician from providing that care.

During oral arguments on April 24, 2024, the justices were sharply divided, and what and if the majority will hold is unclear.

Abortion Medication

FDA Action re Mifepristone	
2000 Mifeprex Approval with Restrictions	Dosage and Administration: Three (3) 200 mg tablets, followed 48hours 400mcg oral misoprostol (1) limits use through 49 days gestation (7 weeks); (2) requires three in-person office visits, one to administer mifepristone, second to administer misoprostol, third to assess complications and ensure no fetal remains in womb; (3) requires the supervision of a qualified physician; and (4) requires the reporting of all adverse events from the drugs.
2016 Risk Evaluation and Mitigation Strategies (REMS) Changes	Dosage and Administration: One (1) 200 mg tablet, 24-48 hours 800mcg buccal misoprostol (1) Increases maximum gestational age to 70 days; (2) Reduces required in-person office visits to one; (3) Allows non-doctors to prescribe and administer mifepristone; and (4) Eliminates reporting of non-fatal adverse events.
2019 Generic Approval	FDA approves generic to GenBioPro, Inc.
2021 Mail-Order Non-Enforcement Decision	FDA "enforcement discretion" to allow mifepristone to be mailed during COVID-19.
2023 REMS Modification	FDA permanently removes in-person dispensing requirement and allows certified pharmacies to dispense

FDA v. Alliance for Hippocratic Medicine (2024)

11/18/22
Alliance for Hippocratic Medicine (AHM) files complaint against FDA and requests a preliminary injunction blocking FDA's 2000 approval of Mifepristone while litigation proceeds.

4/7/23
Northern District Court of Texas, Judge Kacsmaryk grants AHM's request & blocks FDA's approval while litigation proceeds effective 4/14/23.

4/10/23
FDA & Danco request 5th Circuit stay order pending appeal.

4/13/23
5th Circuit issues partial stay not blocking original 2000 approval but blocking FDA actions starting in 2016.

4/14/23
FDA & Danco request SCOTUS stay order pending appeal.

4/21/23
SCOTUS stays Northern District of Texas order pending appeal.

8/16/23
5th Circuit ruled on the merits, declining to invalidate the original approval but upholding the district court's decision with respect to FDA's more recent actions.

9/8/23
FDA and Danco file petition for certiorari with SCOTUS.

3/26/24
Oral arguments.

SCOTUS REVIEW: *FDA v. Alliance for Hippocratic Medicine (2024)*

Questions Presented:

1. Whether respondents have Article III standing to challenge the Food and Drug Administration's 2016 and 2021 actions with respect to mifepristone's approved conditions of use;
2. Whether the FDA's 2016 and 2021 actions were arbitrary and capricious; and
3. Whether the district court properly granted preliminary relief.

During oral arguments on March 26, 2024, SCOTUS indicated that the majority of the court was skeptical that the plaintiffs had standing given their conscientious objection rights and protections.

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California Laws re Reproductive Health

2022 California Proposition 1

- Proposition to amend the California constitution to explicitly grant the right to an abortion and contraceptives

Statutory Right to Abortion
(CA HSC § 123462)

- Every pregnant individual or individual who may become pregnant has the fundamental right to choose to bear a child or to choose to have and to obtain an abortion, except as specifically limited by this article.
- (c) The state shall not deny or interfere with the fundamental right of a pregnant individual or an individual who may become pregnant to choose to bear a child or to choose to have and to obtain an abortion, except as specifically permitted by this article.

Limitations on Abortions After Viability
(CA HSC § 123468)

- Abortion is unauthorized if abortion is performed on a viable fetus, and both of the following are established:
- (1) In the good faith medical judgment of the physician, the fetus was viable.
- (2) In the good faith medical judgment of the physician, continuation of the pregnancy posed no risk to life or health of the pregnant person.

Protections for Assisting a Pregnant Person and for Clinicians Providing Abortions
(CA HSC § 123467; CA BPC § 850.1)

- A person who aids or assists a pregnant person in exercising their rights under this article shall not be subject to civil or criminal liability or penalty, or otherwise be deprived of their rights, based solely on their actions to aid or assist a pregnant person in exercising their rights under this article with the pregnant person's voluntary consent.
- A licensing board shall not deny an application based on another state's law that would be lawful if provided in California

NP, PA, CNM Scope of Practice
(CA BPC §§ 2725.4 3502.4, 3527.5 (**SB 385 (2023);** SB 1375 (2022));

- Law allows NPs, PAs and Certified Nurse Midwives (CNMs) to perform abortions by aspirations techniques without the presence of a supervising physician provided they have certain training.
- Prohibits licensure action against a PA in California for licensure or legal action against a PA in another state related to the performance of an abortion.

Shield Laws
(CA HSC § 123467.5, CA Penal Code §§ 187, 847.5, CA BPC § 850.1);

- A law of another state that authorizes a person to bring a civil action against a person or entity that does any of the following is contrary to the public policy of this state and the state shall not apply or enforce such laws in California.
- Prohibits the issuance of warrants for the provision of reproductive health care, and other requirements related to out-of-state subpoenas for reproductive healthcare information.

Health Plan Coverage Reqs and Non-Discrimination
(CA HSC § 1367.251; CA Insurance Code 10123.1961; CA HSC § 1375.61)

- A health care service plan, shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on coverage for all abortion and abortion-related services, including preabortion and followup services.
- A health plan cannot discriminate against an enrollee based on their receipt of abortion related services.

Right to Refuse to Participate in Abortions
(CA HSC § 123420)

- No employer or other person shall require a physician, a registered nurse, a licensed vocational nurse, or any other person employed or with staff privileges at a hospital, facility, or clinic to directly participate in the induction or performance of an abortion, if the employee or other person has filed a written statement with the employer or the hospital, facility, or clinic indicating a moral, ethical, or religious basis for refusal to participate in the abortion.

Reproductive Health Privacy
(AB 352, AB 254; to be codified at CA Civil Code 56.101, 56.05)

- Enacted data privacy and enhanced security provisions, including requiring businesses (July 1, 2024) and providers (January 31, 2026) to develop capabilities, policies and procedures for medical information on the provision of sensitive services
- Adds "reproductive or sexual health application information" to the definition of "medical information" under CMIA.

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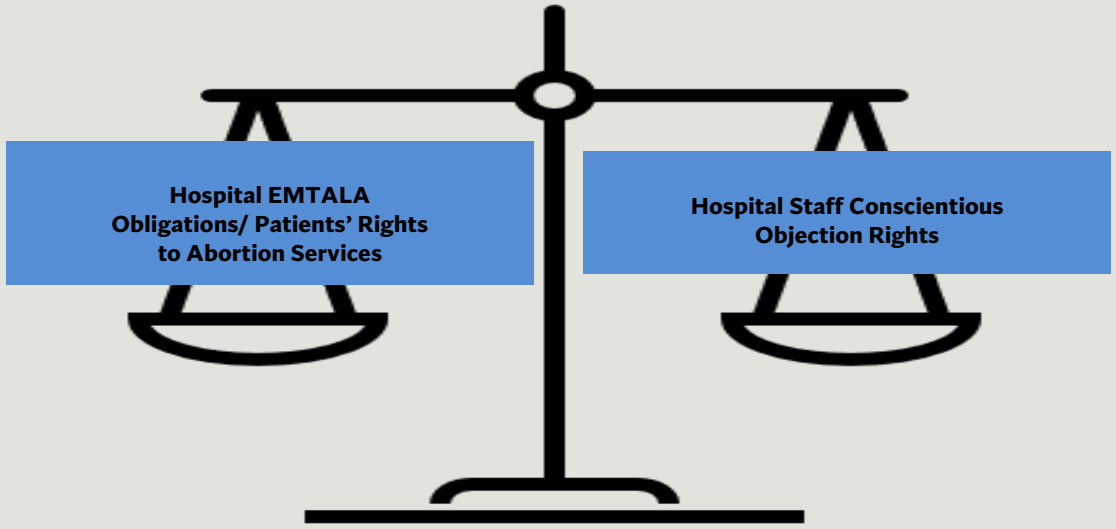
What does this all mean for California hospitals?



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Questions?

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Thank you

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