# Legal Hot Topics


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# Agenda

- What's New in State & Federal Law
  - New Laws
  - Employment Law Update
  - New Regulations
  - New Court Cases Impacting Healthcare & Hospitals

(not necessarily in that order)



# HB 4

- Regulates the collection, use, processing and treatment of consumers' personal data by certain businesses, including biometric data and health care records.
- Affected data may include demographic, genetic, geolocation or any other information that is linked or reasonably linkable to a person.
- Applies to all Texas businesses, except for state agencies and political subdivisions, *institutions of higher education, most nonprofit organizations or covered entities or businesses associates governed by the federal Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act*.
- Certain information is excluded, including protected health information covered by HIPAA, health records, certain patient identifying information, information created and protected by the federal Patient Safety and Quality Improvement Act, data that is de-identified, converted to a limited data set, or collected and used for public health activities pursuant to HIPAA and certain information connected to human subjects and other research.

# HB 4

A consumer may contact a covered business, through the person responsible for the covered data for the business and, among other rights, request:

- Confirmation of the business's possession and access to covered data.
- Correction of inaccuracies in the covered data.
- Deletion of covered data.
- A copy of the covered data.
- An opt out of the processing of covered data for advertising, sale, or other related purposes.

The covered business must deny or comply with a request without undue delay and within 45 days of receiving such request.

If denying a request, justification for the denial and instructions on how to appeal must also be provided. Information requested must be provided free of charge at least twice per year, unless the business can demonstrate the request is manifestly unfounded, excessive or repetitive.

# HB 4

- Must establish two or more secure and reliable methods for consumers to submit requests and may require a customer to utilize an existing account. If the business maintains a website, a mechanism on such site must be provided.
- Must limit the collection of personal data to what is adequate, relevant, and reasonably necessary and must maintain reasonable administrative, technical and physical data security practices.
- Consumers must be provided with a reasonably accessible and clear privacy notice, as required by HB 4.
- Must undertake and document a data protection assessment to, among other things, identify and weigh the benefits and risks of collecting, processing or selling consumer information. De-identified data must remain confidential and unidentifiable.
- AG has exclusive authority to enforce these requirements and must post additional information on its website. Civil penalties may not exceed $7,500 per violation, and penalties may include recovery of attorney's fees and other reasonable expenses. There is no private right of action.

# SB 271

- Adds local gov't entities to gov't entity breach reporting statute
- Requires reporting under B&C Code 521
- Requires Security Incident reporting to DIR, and follow up reporting

# Texas Special Session Update



# Senate Bill 4 – State Criminal Penalty for Illegal Presence or Entry

- Creates a new state crime for people who enter or reenter the US illegally or refuse to comply with an order to return. (*New. Ch. 51 – Penal Code*).
- Law enforcement cannot enforce the law against an undocumented patient while the patient is in the hospital to receive medical treatment or patients at SAFE ready facilities who are receiving a forensic exam and treatment.
- Exception does not apply to family members or others accompanying the patient.
- "Health care facilities" includes hospitals, labs, mental health facilities, intermediate care facilities, transplant centers, facilities for people with intellectual or developmental disabilities.

# Senate Bill 4 – State Criminal Penalty for Illegal Presence or Entry

- Provides Local gov't and state employees, officials, and contractors with immunity from damages liability for actions taken to enforce the law.
- Local gov'ts and the state has to indemnify for attorney's fees.
- Does not apply to employees who act in bad faith, with conscious indifference, or recklessness.
- Would apply to hospital districts and state hospitals.

# Senate Bill 4 – State Criminal Penalty for Illegal Presence or Entry

- Law is being challenged by the DOJ (Jan. 3) and civil rights groups (Dec. 2023). Both cases are in federal court.
  - Argues SB 4 is unconstitutional and/or pre-empted by federal law.
- Unless federal courts temporarily halt enforcement, law will go into effect on or around Mar. 8.
- Public hospitals need to consider:
  - Discussing enforcement with local law enforcement;
  - Review of policies and procedures on HIPAA and disclosures by staff to law enforcement;
  - Additional Staff training on law enforcement disclosures and how to engage with law enforcement that arrives at your facility; and
  - The impact on safe discharge policies and procedures.

# Senate Bill 7 – No COVID Vaccine Mandates by Private Employers

- Creates new Chapter 81D (Texas Health and Safety Code), establishing a prohibition against an employer taking certain action with regards to COVID-19 vaccination requirements for employees, contractors, or applicants.
- Specifically, an employer may not adopt or enforce a mandate requiring an employee, contractor, or applicant for employment or contract position to obtain a vaccination against COVID-19 as a condition for any employment or contract position. Furthermore, an employer cannot take any adverse action against an employee, contractor, or applicant for employment or contract position for any refusal to obtain a vaccination against COVID-19.
- "Employer" is defined as any person, other than a governmental entity, who employs one or more employees. "Adverse action" is defined as an action taken by an employer that a reasonable person would consider was for the purpose of punishing, alienating, or otherwise adversely affecting an employee, contractor, or applicant for employment or contract position.

# Senate Bill 7 – No COVID Vaccine Mandates by Private Employers

- SB 7 contains a limited exception for healthcare facilities, providers, or physicians. This exception allows for the establishment and enforcement of a reasonable policy which includes requiring the use of protective medical equipment by an individual (who is an employee or contractor) and who is not vaccinated against COVID-19. The policy should consider the level of risk the unvaccinated individual presents to patients, based on their routine and direct exposure to patients. Such policy is not an "adverse action" under SB 7.
- An employee, contractor, or applicant for employment or contract position may file a complaint where an employer takes an adverse action in violation of SB 7. The complaint must be filed with the Texas Workforce Commission, in the form and manner described by the Commission, but must include the name of the complainant, the name of the employer, and the nature and description of any alleged adverse action the employer took against the complainant.



# Senate Bill 7 – No COVID Vaccine Mandates by Private Employers

The Commission will investigate upon receipt of a complaint, to determine whether the employer took an adverse action against the complainant because of the complainant's refusal to be vaccinate against COVID-19. When the compliant is against a healthcare facility, provider, or physician, the Commission shall consult with the Department of State Health Services to determine if a policy was reasonable in its adoption and enforcement, in compliance with SB 7.

The Commission may request the Attorney General bring an action for injunctive relief against the employer, to prevent further violations by the employer. Any such action must be filed in district court in Travis County or the county in which the alleged adverse action took place. In any such injunction, the court may include reasonable requirements to prevent further violations.

The Commission may impose an administrative penalty in an amount equal to $50,000.00 for each violation, unless the employer (1) hires the applicant for employment or offers a contract to the applicant for contract position; or, (2) reinstates the employee or contractor, provides back pay from the date the employer took the adverse action, and makes every reasonable effort to reverse the effects of the adverse action – including reestablishing employee benefits for which the employee or contractor otherwise would have been eligible if the adverse action had not been taken.

After investigation establishing violation of SB 7's provisions, the Commission may recover reasonable investigative costs incurred by the Commission in conducting the investigation, regardless if the employee took corrective measures to counteract any adverse action

# SB 29 (88R) and Vaccine Preventable Disease Law

-SB 29 prohibited governmental entities in Texas from implementing or imposing a COVID-19 vaccine mandate (currently no health care exception)

-H&S Code Ch. 224 still requires VPD policy – applies to ees, individuals providing direct care under contract, and individuals with privileges; Policy must list which ACIP diseases require mandatory vaccination and which individuals are required to received vaccines, "based on the level of risk the individual presents to patients by the individual's routine and direct exposure to patients;" Ch. 224 allows for medical and religious/conscience-based exemptions and requires protective equipment be used by exempt individuals

-Can COVID-19 be included in VPD policy?

# Employment Law Update



# ACCOMMODATION ISSUES

- Religious accommodation
  - Undue hardship
  - Other Title VII rights

# ACCOMMODATION ISSUES

- Pregnant Worker & Fairness Act
  - known limitations related to pregnancy, childbirth, or related medical conditions
  - Level of severity

# ACCOMMODATION ISSUES

- Pregnant Worker Fairness Act
  - Qualified/performing essential function/40 weeks
  - Supporting documentation

# ACCOMMODATION ISSUES

- Pregnant Worker & Fairness Act
  - Preferred accommodation
  - Interactive process

# NON-COMPETE UPDATE

- FTC proposed rule
- NLRB Gen Counsel position
- Current law in Texas



# Reproductive Rights & Abortion Law Update

# Abortion Law Update

- Background
  - *Dobbs v. Jackson Women's Health Organization (June 2022)*
    - The Constitution does not confer a right to abortion; *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey* are overruled; the authority to regulate abortion is "returned to the people and their elected representatives".
  - Texas Trigger Law (Health and Safety Code chapter 170A)
    - Enacted in 2021
    - Became effective Aug. 2022 (30 days after final judgment issued in *Dobbs*)
    - "A person may not knowingly perform, induce, or attempt an abortion."
    - "Abortion" means [acting] with the intent to cause the death of an unborn child of a woman known to be pregnant.
    - An act is not an abortion if the act is done with the intent to:
      - save the life or preserve the health of an unborn child
      - remove a dead, unborn child whose death was caused by spontaneous abortion
      - remove an ectopic pregnancy.

# Abortion Law Update

- Texas Trigger Law (Health and Safety Code chapter 170A) (cont.)
  - Penalties
    - Second degree felony, but first degree if the unborn child dies
    - $100K civil fine enforced by the Attorney General
    - Licensing agency must revoke the doctor or other health professional's license.
  - Exception:
    - Performed by a licensed physician
    - In the exercise of reasonable medical judgment, the pregnant female has a life-threatening physical condition aggravated by, caused by, or arising from a pregnancy at risk of death or poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed or induced
    - Is performed in a manner that, in the exercise of reasonable medical judgment provides the best opportunity for the unborn child to survive unless that would create a greater risk of the pregnant female's death or a serious risk of substantival impairment of a major bodily function
  - Other Laws
    - "Heartbeat Law" (H&S Code ch. 171, Subchapter H) that prohibits abortion after about six weeks of pregnancy (2021)
    - Pre-Roe criminal ban (Tex. Civ. Statutes art. 4512.1-4512.6) (1857 and 1925)



# Abortion Law Update

- Zurawski, et al. v. State of Texas, et al.
  - Filed in district court in Travis County (3/6/23)
  - Seeks to clarify the scope of the "medical emergency" exceptions under its abortion bans
  - Filed on behalf of seven original plaintiffs
    - Five Texas women denied abortion care and who as a result faced risks to their health, fertility and lives
    - Two Texas obstetrician-gynecologists
  - Injunction blocking Texas's abortion bans as they apply to dangerous pregnancy complications issued by district court (8/4/23)
    - Clarifies that doctors can use their own medical judgment to determine when to provide abortion care in emergency situations
    - Found S.B. 8 unconstitutional. The judge recognized in her ruling that the women who brought this case should have been given abortions
  - State immediately appealed the ruling to the Texas Supreme Court, blocking it from taking effect
  - Oral arguments held 11/28/23, decision is pending



# Abortion Law Update

- *In re State of Texas*
  - Kate Cox received fetal diagnosis of trisomy 18 at 20 weeks
  - Sought permission from district court in Travis County to terminate pregnancy
  - District Court granted temporary restraining order on 12/7/23 prohibiting Attorney General from enforcing abortion laws
  - State appealed to Texas Supreme Court



# Abortion Law Update

- *In re State of Texas*
  - Supreme Court reversed trial court, ordered the TRO vacated (12/11/23)
    - "A woman who meets the medical-necessity exception need not seek a court order to obtain an abortion. Under the law, it is a doctor who must decide that a woman is suffering from a life-threatening condition…"
    - "The law leaves to physicians—not judges—both the discretion and the responsibility to exercise their reasonable medical judgment, given the unique facts and circumstances of each patient."
    - By requiring the doctor to exercise "reasonable medical judgment," the Legislature determined that the medical judgment involved must meet an objective standard.
      - The statute requires that judgment be a "reasonable medical" judgment
      - Judges do not have the authority to expand the statutory exception to reach abortions that do not fall within its text under the guise of interpreting it.
      - The trial court erred in applying a different, lower standard instead of requiring reasonable medical judgment.
  -



# Abortion Law Update

- *In re State of Texas*
  - Though courts may not expand the statute beyond the Legislature's remit, limiting a physician's judgment by construing the exception more narrowly than the statute provides would likewise be error.
  - For example, the statute does not require "imminence" or, as Ms. Cox's lawyer characterized the State's position, that a patient be "about to die before a doctor can rely on the exception."
  - The exception does not hold a doctor to medical certainty, nor does it cover only adverse results that will happen immediately absent an abortion, nor does it ask the doctor to wait until the mother is within an inch of death or her bodily impairment is fully manifest or practically irreversible.
  - The exception does not mandate that a doctor in a true emergency await consultation with other doctors who may not be available.
  - The courts cannot go further by entering into the medical-judgment arena. The Texas Medical Board, however, can do more to provide guidance in response to any confusion that currently prevails. Each of the three branches of government has a distinct role, and while the judiciary cannot compel executive branch entities to do their part, it is obvious that the legal process works more smoothly when they do.



# Abortion Law Update

- *Petition to the Texas Medical Board for Rulemaking*
  - Filed 1/16/24 by two Austin attorneys Steve and Amy Bresnan under Government Code §2001.021
  - **Requests the TMB to engage in rulemaking to "provide clear guidance to physicians and pregnant females"**
  - **Cite the Texas Supreme Court's call for action in the Cox case**
  - Requests that the TMB utilize consultation processes and hold a public hearing
  - Petition requests a complete and detailed explanation from TMB of its reasoning if it declines to engage in rulemaking
  - By law the TMB has 60 days to commence rulemaking or deny the petition in writing stating its reasons for the denial

# End-of-Life



# House Bill 3162 – Omnibus End-of-Life Legislation

HB 3162 makes broad changes to the Texas Advance Directives Act (TADA) found at Chapter 166, Health and Safety Code. Some of the changes to the TADA include:

- Extending the statutory period for notice to a patient, or their appropriate decision-maker, in advance of a meeting held pursuant to the dispute resolution process set forth in Section 166.046, from 48 hours to 7 days, and specifying certain information that must be included in the notice.
- Requiring an ethics or medical committee to consider the patient's well-being in conducting its review under Section 166.046 but prohibiting any judgment on the patient's quality of life, and enumerating specific considerations the committee must make related to the continuation of life-sustaining treatment – such as whether the treatment will prolong the natural process of dying or hasten the patient's death.
- Specifying and expanding the rights of persons participating in a committee meeting under Section 166.046, before, during, and after the meeting.
- Barring certain persons from participating in an executive session of a committee meeting.
- Clarifying language regarding patients with disabilities, as well as how such disabilities may affect the process and decisions made under the TADA. Specifically, during the review process under Section 166.046(b), an ethics or medical committee is prohibited from considering a patient's disability that existed before the patient 's current admission unless the disability is relevant in determining whether the medical or surgical intervention is medically appropriate.

- Extending from 10 days to 25 days the statutory period for continued attempts to transfer a patient and the provision of care and interventions to a patient after the meeting held pursuant to the dispute resolution process set forth in Section 166.046 deems that ongoing care and interventions are medically inappropriate.
- Expanding and specifying new requirements related to attempts to transfer a patient.
- Clarifying that Section 166.046 applies only to care and treatment decisions for patients who are deemed incompetent or otherwise mentally or physically incapable of communication.
- Introducing a requirement for facilities to report certain data, within 180 days of initiating the dispute resolution process under Section 166.046 and requiring HHSC to publish aggregated data related to these reports.
- Adding language to statute concerning the transfer of patients and, under certain circumstances, limited surgical interventions to help facilitate the patient's transfer.
- Amending language in Chapter 166, Subchapter E, Health and Safety Code (“Facility DNR Orders”) to clarify and correct issues of concern made apparent since implementation in 2017, including those related to potential liability protection.



# Revisions to the Consent to Medical Treatment Act

HB 3162 also amends the Consent to Medical Treatment Act (Chapter 313, Health and Safety Code) to more closely align its decision-making hierarchy with the TADA (Sec. 166.039, Health and Safety Code). Chapter 313 governs treatment decisions made on behalf of an adult patient of a home and community support services agency or in a hospital or nursing home, or an adult inmate of a county or municipal jail who is comatose, incapacitated, or otherwise mentally or physically incapable of communication – and only applies if the patient does not have a legal guardian or an agent under a medical power of attorney who is reasonably available after a reasonably diligent inquiry.

It also removes from the surrogate decision-making hierarchy "the individual clearly identified to act for the patient by the patient before the patient became incapacitated or a member of the clergy."

Finally, under a new subsection added to Section 313.004, if the patient does not have a legal guardian, an agent under a medical power of attorney, or a person listed in the hierarchy listed in Subsection (a) (*i.e.*, spouse, adult children, parents, or nearest living relative who is reasonably available after a reasonably diligent inquiry), another physician who is not involved in the medical treatment of the patient may concur with the proposed treatment.



# HHS/Office of Civil Rights Privacy Update



# HIPAA, OCR Bulletin, and AHA Litigation

- Background
  - The Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations strike a balance between protecting the privacy of people who seek care and healing,  while permitting important uses of information.
    - "A major goal of the Privacy Rule is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well being." See generally Summary of the HIPAA Privacy Rule
  - December 2022, U.S. HHS Office for Civil Rights (OCR) issues informational bulletin entitled "Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates" (the "Bulletin")

# HIPAA, OCR Bulletin, and AHA Litigation

- Background
  - OCR's position:
    - When an online technology connects (1) an individual's IP address with (2) a visit to an Unauthenticated Public Webpage that addresses specific health conditions or healthcare providers, that combination of information (the Proscribed Combination) is subject to restrictions on use and disclosure under HIPAA
  - July 2023
    - OCR contacted 130 hospital systems and telehealth providers "strongly encourag[ing]" them "to review" and "take actions" in light of "OCR's December 2022 bulletin" and warning them that it is "closely watching developments in this area."
    - OCR Press Release:
      - The agency is "concerned" that hospitals' use of these technologies results in "impermissible disclosures of health information, " an issue that OCR "will use all of its resources to address."
  - Sept. 1, 2023
    - OCR publicly released the names of all hospitals and health systems that received its July 2023 warning letter.



# HIPAA, OCR Bulletin, and AHA Litigation

- *American Hospital Association, Texas Hospital Association, Texas Health Resources, and United Regional Health Care System v. OCR*
  - Filed 11/2/2023 in federal district court, Northern District of Texas
  - Allegations include:
    - (1) The rule expressed in the Bulletin related to Proscribed Combinations exceeds the statutory authority under HIPAA and is contrary to law when it concluded that a Proscribed Combination constitutes "individually identifiable health information"
      - If a public-health researcher may use her personal computer to search a hospital's webpage for the availability of dialysis appointments, the technology's combination of (1) the researcher's IP address and (2) the visit to a page addressing dialysis appointments would, according to the Bulletin, be subject to HIPAA's requirements
      - If the technology combined (1) the IP address of an individual who used his personal computer on behalf of an elderly neighbor (2) to read a hospital's webpage with information about the onset of Alzheimer's disease, that is covered by HIPAA



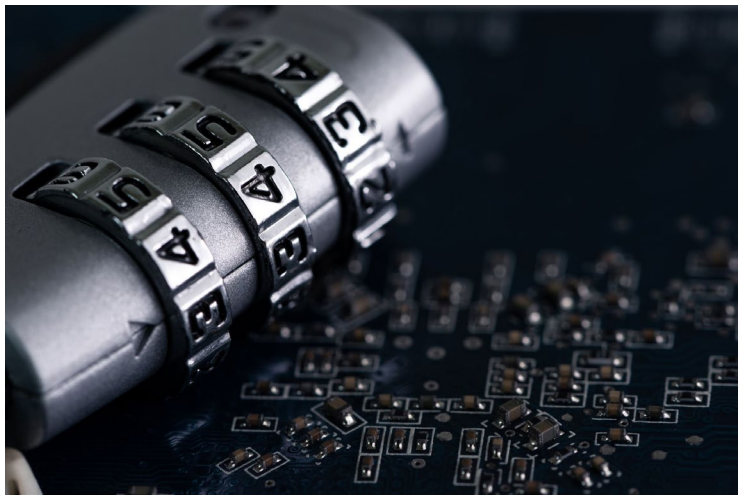
# HIPAA, OCR Bulletin, and AHA Litigation

- *American Hospital Association v. OCR* (cont.)
  - (2) The Bulletin's rule that the Proscribed Combination constitutes IIHI constitutes arbitrary and capricious rulemaking
    - OCR provided no reasoning for its assertion that the IIHI definition is satisfied by the "indicative" "connection" that purportedly exists between an individual who visits a hospital's Unauthenticated Public Webpage and the specific health-related information on that webpage.
  - (3) The Bulletin's rule that the Proscribed Combination constitutes IIHI is a legislative rule for which OCR was required to, but did not, undertake notice-and-comment rulemaking under the Administrative Procedures Act
    - The Bulletin speaks with the force of law to condemn a new category of conduct, creating a novel, binding norm that dramatically shifts healthcare providers' obligations under HIPAA and significantly affects their interests.
  - Requests that the Bulletin be set aside insofar as it provides that the Proscribed Combination is IIHI, a declaratory judgment that the Proscribed Combination does not constitute IIHI under the statutory and regulatory definition, and permanent injunctive relief enjoining OCR from enforcing against the hospitals and the associations' other members the rule in the Bulletin that the Proscribed Combination is IIHI
  - Motion for Summary Judgment filed 1/5/24



# New HIPAA Regulations on Reproductive Healthcare Privacy

- On April 17, 2023, OCR published proposed rules to amend the HIPAA Privacy Rule to limit when PHI can be disclosed where the use or disclosure is about reproductive health care.
- Executive Order 14076- President Biden directed HHS to consider taking actions to protect health information related to reproductive healthcare and strengthen patient/provider confidentiality.
- Final Rule expected in March, 2024.



# New HIPAA Regulations on Reproductive Healthcare Privacy

- Prohibits the use or disclosure of PHI for either of the following purposes:
  - Criminal, civil, or administrative investigation/proceeding into any person in connection with seeking, obtaining, providing, or facilitating reproductive health care, *where the care is lawful under the circumstances in which it is provided.*
  - The identification of any person for the purpose or initiating such investigations or proceedings.

# New HIPAA Regulations on Reproductive Healthcare Privacy

- Applies to the following situations:
  - Where the care is lawful and occurs outside of the state where the investigation or proceeding is authorized.
    - Ex:  Texas resident travels to Colorado for reproductive health care/abortion.
  - The care is protected, required, or expressly authorized by federal law regardless of the state.
    - Ex: Miscarriage management provided under EMTALA to stabilize the health of a pregnant woman.
  - The care provided in the state where the investigation/proceeding is authorized AND is lawful in that state.
    - Ex: Reproductive health care provided to remove an ectopic pregnancy and such care is lawful in that state.

# New HIPAA Regulations on Reproductive Health Care Privacy

- Would still allow disclosures of PHI related to reproductive health care if the request is not made primarily for the purpose of investigating or imposing liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
  - Use PHI in defense against professional misconduct or negligence claims
  - Use in defense in criminal, civil, or administrative proceedings.
  - Disclosures to the OIG during an audit for health oversight purposes.

# New HIPAA Regulations on Reproductive Health Care Privacy

- Would require covered entities to attest when requests for reproductive health care are received to obtain a signed attestation that the use or disclosure is not for a prohibited purpose. Requirement would apply to the following situations:
  - Health oversight
  - Judicial and administrative proceedings
  - Law enforcement purposes
  - Disclosures to coroners and medical examiners.

# New Case Law: Amicus Briefs Filed by THA & New Texas Supreme Court Decision



# *Renaissance Medical Foundation v. Lugo*

- Defendant Dr. Burke is an employee of RMF, a nonprofit health organization certified by the Texas Medical Board under Tex. Occupations Code sec. 162.001(b) ("NPHO")
- Dr. Burke sued for alleged negligence in connection with a surgery he performed
- RMF also named in the suit, under the doctrine of *respondeat superior*
- RMF contends that it is not vicariously liable for the acts of Dr. Burke
  - Employer vicarious liability rests on the right of the employer to control the manner in which the work is carried out
  - Texas statutes and Texas Medical Board rules expressly prohibit NPHOs from interfering with the practice of medicine:
    - An NPHO "may not interfere with, control, or otherwise direct a physician's professional judgment in violation of this subchapter or any other provision of law, including board rules." Tex. Oc.. Code sec. 162.0021.



# *Renaissance Medical Foundation v. Lugo*

- Trial court denied summary judgment on behalf of RMF
- Court of Appeals affirmed ruling, holding that traditional notions of respondeat superior and vicarious liability apply
- RMF filed petition for review with Texas Supreme Court (discretionary)
- THA *amicus* letter:
  - The Texas legislature has affirmatively prohibited the employing NPHO from exercising any control over medical acts.
  - The impact of this policy on the traditional notion of vicarious liability is, therefore, a novel question that the Supreme Court of Texas should address.
- Texas Supreme Court ordered briefing on the merits, left petition for review pending



# *Wes Gilbreath, Jr. et.al v. Lisa R. Gilbreath Horan, et. al*

- Defendants sought emergency detention warrant for sister under Health and Safety Code sec. 573.011 (imminent substantial risk of serious harm to himself or others due to mental illness if not immediately restrained)
- Warrant issued and sister detained
- Sister released from detention by physician, sued siblings and family business entities for malicious prosecution
- $1.5 million verdict rendered for plaintiff
- Court of appeals affirmed finding that family did not prove at trial that they acted in good faith
- THA argued that Texas Supreme Court should accept the case because of the potential chilling effect it may have on seeking help for individuals in mental health crisis
- Supreme Court declined to hear the case

# *Marsillo v. Dunnick*

- Legal issue: standard of care for emergency medical care provided in a hospital emergency department.
- 13-year-old bitten by rattlesnake and transported to hospital by EMS; doctor immediately implemented snakebite treatment guidelines – taken from recommendations of the American Academy of Family Practice and antivenom manufacturer.
- Antivenom is most effective when given within hours of snakebite, but carries risk of complications.
- Guidelines set out a detailed, seven-part process for patients who present with a snakebite and revolves around a "snakebite severity score."

# *Marsillo v. Dunnick*

- After applying and following the Guidelines, antivenom was administered just over four hours after the snakebite.
- Patient was then transferred to the children's hospital, where additional antivenom and additional care were provided. Patient was discharged the next afternoon; notes indicate "hospital course was uncomplicated."
- Plaintiff and parents sued for negligence, alleging that following the Guidelines (and not providing antivenom sooner) was negligence resulting in pain, suffering, impairment, and disfigurement.
- Trial court granted no-evidence summary judgment on breach of duty and causation, against Plaintiff. Court of appeals reversed.



# *Marsillo v. Dunnick*

- Sec. 74.153(a), CPRC:

  in a suit involving a health care liability claim against a physician . . . for injury to or death of a patient arising out of the provision of emergency medical care in a hospital emergency department, . . . the claimant bringing the suit may prove that the treatment or lack of treatment by the physician . . . departed from accepted standards of medical care . . . only if the claimant shows by a preponderance of the evidence that the physician . . . , with willful and wanton negligence, deviated from the degree of care and skill that is reasonably expected of an ordinarily prudent physician . . . in the same or similar circumstances.

- Texas Legislature has not defined "willful and wanton."



# *Marsillo v. Dunnick*

- Court finds the standard for gross negligence may be applicable, which requires an act or omission:
  - which when viewed objectively from the standpoint of the actor at the time of its occurrence involves an extreme degree of risk, considering the probability and magnitude of the potential harm to others; and
  - of which the actor has actual, subjective awareness of the risk involved, but nevertheless proceeds with conscious indifference to the rights, safety, or welfare of others.
- The court further holds that "willful and wanton" is at least gross negligence.



# *Marsillo v. Dunnick*

- Evidence sufficient to show the decision to follow the Guidelines posed "an extreme degree of risk" and that the physician was aware of the risk but proceeded with conscious indifference was not presented.
- Plaintiff's expert and report did not explain opinions why antivenom should be immediately administered or why risks of administration should not be considered, per the Guidelines.
- As Plaintiff's expert failed to address the Guidelines, they failed to explain how course of treatment posed an extreme degree of risk.
- Court reverses the court of appeals' judgment and reinstates trial court's summary judgment against Plaintiff.

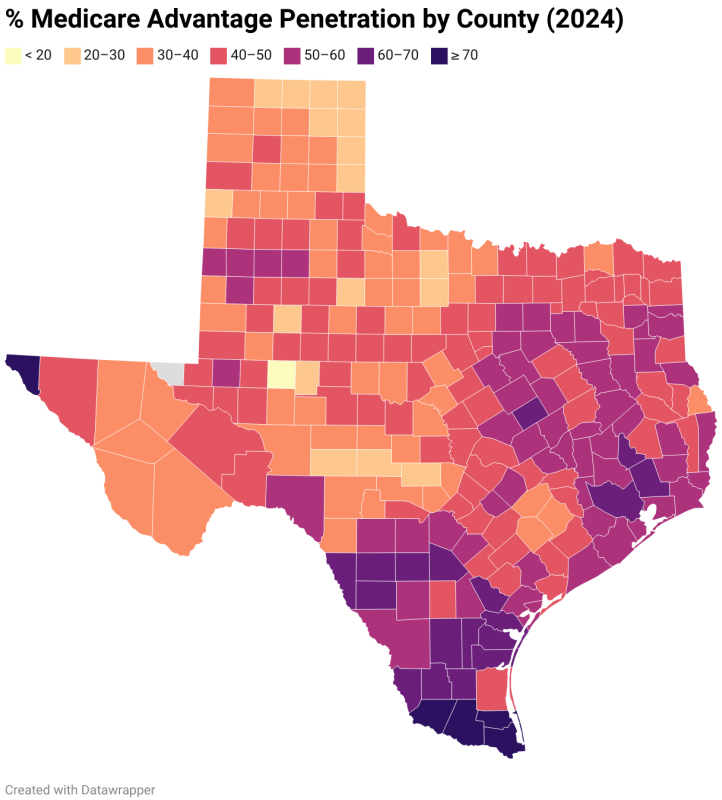


# Medicare Advantage Update



# Medicare Advantage Update

- Medicare Advantage Enrollment is Growing in Texas!



# Medicare Advantage Update

- CMS Rules
  - Policy & Technical Changes for 2024
    - Adopted in April 2023.
    - Generally applicable to coverage that began Jan. 1, 2024.
    - MA plans cannot use internal or proprietary criteria to limit or deny coverage for a Medicare-covered service if their restrictions don't exist in traditional Medicare.
    - MA plans must adhere to the "Two-Midnight Rule" for inpatient admissions if the admitting physician believes expects they will require care that crosses two midnights.
    - Health plan clinicians reviewing prior authorization requests have to have expertise in the relevant medical discipline for the service being requested.
    - Prior auth has to be valid for an entire course of approved treatment and for a 90-day transition period if the enrollee switches MA plans.



# Medicare Advantage Update

- CMS Rules
  - Interoperability and Prior Authorization Rule
    - Impacted Payers: MA, State Medicaid FFS, Medicaid Managed Care, State CHIP, CHIP managed Care, and Qualified Health Plans on the Federally Facilitated Exchanges (QHPs).
    - Mandates Impacted Payers implement a Provider access API; Payer-to-Payer API; and Prior Authorization API by Jan. 1, 2027.
    - Updates the requirements for Patient Access API – must make certain prior authorization information available on this API within 1 business day from the request date by Jan. 1, 2027.
    - Improves Prior Authorization Processes
      - Begins Jan 1., 2026 impacted payers have to provide a specific reason for a denial of a prior authorization request.
      - Impacted Payers (except QHPs) must communicate their prior auth decisions no later than 7 days for a standard request and 72 hours for an expedited request. Does not apply to prior authorization for drugs.

# Medicare Advantage Update

- CMS Rules
  - Interoperability and Prior Authorization Rule
    - The Prior Authorization API must include a list of payer's covered items and services (excluding drugs) that require prior authorization, identify all required documentation for approval, be HIPAA compliant, and communicates the decision on the request including the specific reason.
    - Beginning in 2026 Impacted payers must publicly report a list of aggregated prior authorization metrics on their websites every year by March 31.
    - Allows for State Medicaid, CHIP FFS and QHPs to apply for an extension or exemption from the compliance date for the APIs.
    - Beginning in CY 2027 – if you are an eligible hospital or Critical Access Hospital (CAH) participating in the Medicare Promoting Interoperability Program (MIPS) you can report on the electronic prior authorization measure using a yes/no attestation on whether you submitted at least one prior auth request via a Prior Auth API using data from your certified electronic health record technology. A hardship exception is available for certain eligible hospitals and CAHs. If you fail to report "yes" that will result in downward payment adjustment.



# Medicare Advantage Update

- Shortly after the April Policy and Technical Rule was released, AHA began to receive concerns that certain Medicare Advantage Organizations indicated that they did not intend to make changes to comply with the new rule.
  - Changing terminology in denial letters.
  - Using additional insurer criteria to supplement the Medicare criteria for inpatient admissions.
  - Using Milliman Clinical Guidelines to evaluate inpatient admissions.
- AHA requested CMS clarify their rules in order to prevent MAOs from continuing their policies to circumvent the rules.

# Medicare Advantage Update

- Advocacy Efforts Ongoing at THA
  - Submitted a response to an RFI on Rural Health to the House Ways & Means Committee
  - Submitted a response to the House Budget Committee RFI
  - Working with Congressman Arrington's office on federal legislation to keep cost-based reimbursement for CAHs when they see MA patients.



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# Medicare Advantage Update

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By Casey Ross and Bob Herman

March 13, 2023

# Questions



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