


	<h2 data-bbox="743 674 1040 764">Legal Update for Risk Managers</h2> <p data-bbox="743 814 1105 869">September 30, 2020 Melissa Hauer   General Counsel/VP</p>
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	<h2 data-bbox="829 1209 1084 1262">Disclaimer</h2> <p data-bbox="683 1377 1149 1436">This presentation is intended to convey general information only.</p> <p data-bbox="683 1476 1203 1535">The contents should not be construed as, and should not be relied upon for, legal advice.</p> <p data-bbox="683 1575 1162 1633">Contact your attorney for advice on your specific circumstances.</p>
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	Legal Issues Update
	COVID-19 Regulatory Changes
	Q & A

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	LEGAL UPDATES
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<h2>Legal Issues</h2>		
<h3>TOPICS</h3>		
ACA lawsuit (CA v. TX)	Recent litigation involving hospitals	Future State

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<b>CA v. TX ACA Lawsuit</b>	<ul style="list-style-type: none"><li>• Case was initiated by a group led by TX Attorney General, joined by other Republican state attorneys general, including ND Attorney General Stenehjem.</li><li>• Backed by Trump Administration Justice Dept.</li><li>• Alleges that when Congress in 2017 zeroed out the tax penalty for people who don't buy health insurance, it rendered unconstitutional the entire ACA.</li></ul>
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<p>CA v. TX ACA Lawsuit</p>	<ul style="list-style-type: none"><li>• The lower court found the individual mandate to be unconstitutional as well as the entire ACA.</li><li>• The 5<sup>th</sup> Circuit Court of Appeals upheld the lower court's decision but sent the case back for an analysis of whether the rest of the law can remain (be "severed").</li><li>• The case was appealed to the U.S. Supreme Court</li></ul>
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<p>CA v. TX ACA Lawsuit</p>	<ul style="list-style-type: none"><li>• Death of Justice Ginsburg leaves uncertainty.</li><li>• Case is now before an eight-member court.</li><li>• President Trump nominated a new justice.</li><li>• The Senate appears poised to move quickly with confirmation proceedings.</li><li>• It is unclear whether that can be accomplished before oral argument on November 10.</li></ul>
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<p>CA v. TX ACA Lawsuit</p>	<ul style="list-style-type: none"><li>• Justice Ginsburg was considered a reliable vote to uphold the ACA.</li><li>• The sudden change provides a better chance of overturning the ACA - but not a certainty.</li><li>• Chief Justice Roberts and Justice Kavanaugh recently authored opinions in other cases that found parts of laws can be invalidated while leaving the rest in place.</li><li>• Congress has made several targeted changes to the ACA in recent years but left the rest of the law alone.</li></ul> <p style="text-align: center;"></p>
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	<h2>Recent Litigation Involving Hospitals</h2>
<p>Avoiding Noneconomic Damages Caps</p>	<ul style="list-style-type: none"><li>• “Hybrid” lawsuits alleging claims in addition to professional negligence are being brought to avoid noneconomic damages caps.</li><li>• A CA jury recently awarded \$9.25 million in non-economic damages to a plaintiff who consented to “local excision of scrotal mass, possible cystoscopy.”</li><li>• The surgeon found that the mass was much larger than anticipated and removed the scrotal mass as well as a significant portion of the patient’s penis.</li><li>• The patient was left with a disfigured and dysfunctional penis and sued the surgeon, claiming that he neither knew nor consented to the removal of additional tissue.<ul style="list-style-type: none"><li>– <i>Burchell v. Faculty Physicians &amp; Surgeons of the Loma Linda University School of Medicine</i></li></ul></li></ul>

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## Recent Litigation Involving Hospitals

### Avoiding Noneconomic Damages Caps

- In addition to medical negligence, patient also claimed medical battery for enduring a very different procedure than he had agreed to.
- This allowed the jury to skirt the state's \$250,000 cap on non-economic damages for professional negligence.
- The jury awarded the plaintiff more than \$9 million in non-economic damages – well above the cap.

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## Recent Litigation Involving Hospitals

### Whistleblower Suits

- Two surgeons sued a hospital system alleging the organization retaliated by firing them for voicing patient safety concerns.
- The surgeons allege they repeatedly raised concerns with senior leadership about the cardiothoracic and organ transplant programs. Among the complaints were allegations of misreported patient deaths and patients who died due to improper medication levels and a lack of actual patient care.
- A third and fourth lawsuit were filed a few months later by another cardiothoracic surgeon and a transplant surgeon alleging similar patient safety concerns. They had also been fired.

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## Recent Litigation Involving Hospitals

### Whistleblower Suits

- One of the physicians was told by the organization that his dismissal was 'based solely on budgetary concerns,' but he was told to immediately stop working and was escorted out by security.
- Scientific Registry of Transplant Recipients July 2019 report showed 14 instances where kidney transplants failed at the medical center, more than double than the expected six.
- A 2019 state Department of Health report noted that patients who had coronary artery bypass graft surgeries, valve replacements or joint bypass/valve-replacement between 2014 and 2016 had a significantly worse survival rate and higher readmission rate than the statewide average.

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## Recent Litigation Involving Hospitals

### Whistleblower Suits

- Evidence of strong internal reporting was effective to protect one health care facility against a claim of retaliation for reporting patient safety concerns in another whistleblower lawsuit.
- The court affirmed a judgment in favor of the hospital at least in part because the hospital had multiple channels for reporting safety and quality concerns.
- The plaintiff did not use any of these channels. The court noted that while the whistleblower statute does not require any formal procedure, the plaintiff at least had to put the employer on notice of his concerns and he failed to do so.

- *Melamed v. Cedars-Sinai Medical Center*

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## Litigation Update

*Future State?*

### EMTALA and COVID-19.

- **Patient Volume.** A hospital in another state is being cited by state surveyors for EMTALA violation due to long screening lines at the ER.
- **Noncooperative Patients.** Hospitals are experiencing patients presenting to the ED who refuse to comply with masking requirements and other safety protocols.
- **Lack of Supplies.** What happens if a patient presents with an emergent condition that needs scarce resources, such as a ventilator, bed for stabilization? EMTALA requires stabilizing treatment for individuals with an emergency medical condition within hospital's capability. Consider implementing alternative protocols, such as manual ventilation to assist in stabilizing patient until appropriate transfer can be arranged.


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## Litigation Update


*Future State?*

- **Visitor restrictions.** End of life issues, developmental disability community push for support persons to be allowed in hospitals.
- **COVID-19 Vaccine.** The Trump administration's Federal Distribution Strategy was issued jointly by the Dept. of Health and Human Services (HHS) and the Dept. of Defense (DoD) for COVID-19 vaccine. How should states allocate it? Distribute it? Bill for it? What about "vaccine hesitancy"? What liability protections exist for providers if patients suffer harm?

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	<p>COVID-19 REGULATORY CHANGES</p>
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<h2>COVID-19 Related Waivers</h2> <p>Health care workers</p> <ul style="list-style-type: none"><li>- Suspension of licensing requirements for certain health care workers (e.g., nurses, pharmacists, physicians, psychologists, OT, social workers, RT, dieticians, lab, EMS, etc.)</li><li>- Subject to identification, verification of credentials and other temporary emergency requirements approved by State Health Officer, Director of Emergency Services, in consultation with ND Department of Human Services.</li></ul> <ul style="list-style-type: none"><li>• ND Gov. Exec. Order 2020-05 (Mar. 19, 2020), 2020-20 (Apr. 3, 2020) (respiratory therapists)</li></ul>	
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## COVID-19 Related Waivers

### Hospitals and other health care facilities

- Suspension of licensing requirements under certain state laws and related administrative rules (chapters 23-01.2 (Trauma and Emergency Medical System); 23-09 (Lodging Establishments and Assisted Living Facilities); 23-09.3 (Basic Care Facilities); 23-16 (Licensing Medical Hospitals); 23-17.3 (Home Health Agency Licensure); 23-17.4 (Hospice Programs); 23-27 (EMS Operations); 50-31 (Substance Abuse Treatment Programs))
- Subject to temporary emergency requirements established by State Health Officer and the Adjutant General, in consultation with the ND Department of Human Services.
  - ND Gov. Exec. Order 2020-05 (Mar. 19, 2020)



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## COVID-19 Related Waivers

### Telehealth

- a. - "Secured connection" NDCC § 26.1-36-09.15 (1)(g)(1) expanded to include CMS March 17, 2020 guidance;
- b. - "Audio-only" provision NDCC § 26.1-36-09.15 (1)(g)(3) suspended;
- c. - Telehealth shall be provided as defined by NDCC § 26.1-36-09.15 (1)(g)(1), (2) to include audio-only telehealth services;
- d. - Insurance carriers must cover virtual check-ins and e-visits for established patients per CMS March 17, 2020 guidance;
- e. - Insurance carriers may not subject telehealth coverage, including virtual check-ins and e-visits for established patients, to deductible, coinsurance, copayment or other cost sharing provisions;
- f. - Insurance carriers may not impose any specific requirements on the technologies used to deliver telehealth, virtual check-in and e-visit services (including any limitations on audio-only or live video technologies) that are inconsistent with these requirements.
  - a. - ND Gov. Exec. Order 2020-05.1 (Mar. 20, 2020)




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## COVID-19 Related Waivers

Hospital licensing

- ND State Health Officer waived licensing requirements and suspended regulatory enforcement of all licensing requirements for hospitals with some exceptions.
- Subject to temporary emergency requirements established by State Health Officer and Adjutant General in consultation with ND Department of Human Services.
- As a result of this temporary waiver, hospitals do not need to submit individual program flexibility requests.
- This waiver is valid through the duration of the declared state of emergency.

- State Health Officer Order Mar. 28, 2020




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## COVID-19 Related Waivers

State Health Officer authority

- Allows the State Health Officer to issue orders relating to disease control measures deemed necessary to prevent the spread of COVID-19 and consistent with due process.


- ND Gov. Exec. Order 2020-14 (Mar. 26, 2020)



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## COVID-19 Related Waivers

- Exemptions for essential workforce who are household contacts of people who test positive for COVID-19 as defined by the US Dept of Homeland Security, CDC.
- State Health Officer Order Apr. 10, 2020




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## COVID-19 Related Waivers

Civil immunity

- Not addressed in ND (yet?)
- Other states provided via legislation or executive order.
- Congress considering



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## COVID-19 Related Waivers

### Civil immunity

- Letter to Gov. Burgum from NDHA, NDMA, NDLTCA on May 13, 2020, requesting liability protection for health care workers during pandemic.
- Protect health care workers by providing limited immunity from civil and administrative liability for harm caused resulting from efforts to reduce the projected loss of lives during pandemic.
- Other liability risks for health care workers and facilities: shortage of specialty physicians, practice outside of normal specialty certification or practice scope.
- Liability protection for shortage of medical equipment like ventilators, PPE, medications, etc. and providers having to allocate among patients.
- Liability issues that arise with a new disease with no established treatment protocols. Medical professionals are using treatment options based on incomplete data, uncertain side effects, and must treat quickly with what is available when resources and choices are restricted or limited.




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## Q & A



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	<p>Thank You.</p> <p>Melissa Hauer   General Counsel/VP (701) 224-9732 mhauer@ndha.org</p>
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