



# Legal Implications of COVID-19: All you can drink in sixty minutes

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# Introduction

- The presentation encompasses many complex rules, etc.
- Impossible to address in much detail in one hour.
- Therefore, focus on identifying some of the key developments, and providing links to helpful resources.



# CMA

- This is not legal advice; it is simply a short overview of a long list of rules.
- Check the rules or talk to your legal advisor before taking any action.



# Overview

- Malpractice liability
- Executive Orders
  - Elective surgery ban and exemption
  - Back to work
- Force majeure
- CMS Programs
  - Provider Relief Fund
  - Waivers
- HIPAA Waivers
- HR issues
- Closing a practice

# Malpractice Risks

“As if the COVID-19 crisis isn't terrible enough, there are some attorneys who are willing to make it worse for physicians.”

Debra Shute, *COVID-19: Malpractice Risks When Treating Patients*, April 29, 2020



# Possible COVID-Related Claims

- Failure to timely diagnose and treat;
- Failure to take precautions to limit the spread of infection;
- Delaying treatment because of infection concerns;
- Going ahead with treatment despite infection concerns;
- Prescribing; and
- Failing to prescribe.

# The good news: PREP immunity

- The Public Readiness and Emergency Preparedness Act (PREP) was enacted in 2005 to protect vaccine manufacturers.
- On March 10, 2020, the DHHS Secretary signed a Declaration extending PREP Act to provide immunity under state and federal law for COVID-19 care provided between February 4, 2020 and October 1, 2024.

# PREP

- The Declaration provides immunity to [Covered Persons] against any claim caused by, relating to, etc. the manufacture, distribution, administration, or use of [Covered Countermeasures], except for claims involving “willful misconduct.”
- "Willful Conduct" means acts or omissions taken:
  - Intentionally, to achieve a wrongful purpose;
  - Knowingly, without legal or factual justification; or
  - In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

# PREP

- “Covered Persons” includes licensed health care professionals.
- "Covered Countermeasure" means a "qualified pandemic or epidemic product" or a drug, biological product or device authorized for emergency use.
- A "qualified pandemic or epidemic product" includes any drug or device specifically designed, used, etc. to treat a pandemic/epidemic or to limit the harm the pandemic would otherwise cause.
- **Note: a Covered Countermeasure must be approved or cleared by FDA, licensed under the Public Health Services Act or authorized for emergency use under the FD&C.**

# EO 2020-27 Good Samaritan

- Licensed health care professionals providing services in connection with the public health emergency are presumed to have acted in good faith, and are immune from liability.
- The EO does not provide immunity for gross negligence or reckless or willful misconduct,
  - Including performing services “under the influence.”
- The immunity survives expiration of the EO.

# The bad news: Arizona Constitution?

## 31. Damages for death or personal injuries

No law shall be enacted in this state limiting the amount of damages to be recovered for causing the death or injury of any person.

# The bad news: hindsight bias

“[P]eople perceive and evaluate events differently once they know about their outcome. One facet of hindsight bias is that people often perceive past events as more foreseeable than they do without outcome knowledge. This finding is of great importance in the legal context. Specifically, negligence judgments are based on the decision-makers’ evaluation of how foreseeable the harm that occurred was.”

*When Being Wise After the Event Results in Injustice: Evidence for Hindsight Bias in Judges’ Negligence Assessments; Psychology, Public Policy & the Law, 2016.*

# The impact of hindsight bias

As a result of hindsight bias, the clinical decisions you made in the midst of a crisis, with great uncertainty ....



# Hindsight

... might be judged harshly by jurors who know all the answers that were unknowable to you.



# Prescribing liability

## Prescriptions Surged as Trump Praised Drugs in Coronavirus Fight

By that evening, first-time prescriptions of the drugs — chloroquine and hydroxychloroquine — poured into retail pharmacies at more than 46 times the rate of the average weekday, according to an analysis of prescription data by The New York Times. And the nearly 32,000 prescriptions came from across the spectrum — rheumatologists, cardiologists, dermatologists, psychiatrists and even podiatrists, the data shows.

New York Times, April 25, 2020

# Early results

- *Small Chloroquine Study Halted Over Risk of Fatal Heart Complications*, NYT, April 12, 2020.
  - Citing Borba, et al., *Preliminary safety results of a randomized, double-blinded, phase IIb clinical trial (CloroCovid-19 Study)*.
- Geleris, et al., *Observational Study of Hydroxychloroquine in Hospitalized Patients with Covid-19*, NEJM May 7, 2020.
  - “[T]he study should not be taken to rule out either benefit or harm of hydroxychloroquine treatment. However, our findings do not support the use of hydroxychloroquine at present, outside randomized clinical trials testing its efficacy.”

# MICA Practice Resources

- Reopening a practice during a pandemic
- On the frontlines...
- Post-COVID practices:
  - Prescription refills
  - Vaccinations
  - Elective Surgeries
  - Telemedicine
- Phishing scams, e.g., emails from “WHO,” “CDC,” etc.

# MedPro Practice Resources

- <https://www.medproCOVID-19.com/medpro-tools>
  - Documentation guidance
  - Patient forms
  - Post-shutdown checklists

# Executive Orders

<https://azgovernor.gov/executive-orders>

- Policies for SNFs, ALFs, etc.
- Coverage for OON lab tests
- COVID testing cost-sharing waivers
- Expanding and encouraging telemedicine
- Price gouging prohibition
- Elective surgery prohibition
  - Elective Surgery Exemption
- Increasing hospital capacity
- Good Samaritan immunity
- Stay healthy, etc. Part I
- Stay healthy, etc. Part II

# Elective Surgery

## Elective surgery prohibition

- EO 2020-10, effective 3/31/20
  - Deference to physician judgment.
  - A surgery should not be deemed non-essential or elective if it would threaten the patient's life, threaten permanent dysfunction or impairment of any body part, risk metastasis or progression of staging, or require the patient to remain hospitalized if the surgery was delayed.

## Exemption

- EO 2020-32, exemption, effective May 1, 2020

# Exemption criteria

ADHS: Executive Order 2020-32 FAQs.

- Greater than 14 day supply of PPE;
- Adequate staffing and beds;
- Testing patients and workers;
- Ensuring appropriate discharge plans;
- Implementing a universal symptom screening process;
- Establishing an enhanced cleaning process; and
- Prioritizing the restart based on urgency.

# Exemption Process

- Submit an online attestation documenting compliance with the criteria;
- ADHS will send you an email confirming receipt; and
- Keep the receipt.

No ADHS audit or confirmation required.

# EO 2020-36

## Stay Healthy, Part II

Businesses are required to develop, establish and implement policies based on guidance from the CDC, DOL, OSHA and ADHS to mitigate the spread, including:

- Promoting hygiene,
- Intensifying cleaning practices,
- Monitoring for sickness,
- Providing protective equipment,
- Allowing for and encouraging teleworking,
- Providing plans to return in phases, and
- Limiting group size.

# Force majeure clauses

- Merriam-Webster defines “force majeure” as: “(1) superior or irresistible force; and (2) an event or effect that cannot be reasonably anticipated or controlled.”
- A “force majeure” clause is designed to excuse a party’s breach of contract based on events outside the party’s control.
- The clauses typically are found in the “boilerplate” section, and they have been the subject of negotiation or discussion.

# Sometimes called “Acts of God”



Commonly used secular terms:

- Natural disasters (such as floods, earthquakes and hurricanes),
- War,
- Terrorist acts, or
- Government action (such as eminent domain or change in laws).

# Elements of the defense

To prevail on a force majeure defense:

- There must be a force majeure provision in the contract, which includes the relevant event, i.e., epidemic, and the event must be a cause of the party's inability to perform.
- Similar defenses include the doctrines of impracticability of performance, frustration of purpose, and impossibility.
- Courts generally do not liberally enforce force majeure clauses.

# CMS Provider Relief Fund

- <https://www.hhs.gov/sites/default/files/provider-relief-fund-general-distribution-faqs.pdf>
- \$100 billion to reimburse providers for lost revenues and increased expenses due to the coronavirus pandemic.
- Distributions calculated based on Medicare FFS billings.
- General distributions and targeted distributions.
- No need to repay if T&C are met.

# Provider Relief Fund

## Allocation

- A provider can estimate the PRF payment by dividing their 2019 Medicare FFS payments they received by \$484,000,000,000, and multiply that ratio by \$30,000,000,000.

## Attestation and Acceptance of Terms and Conditions

- Within 30 days of receiving the payment, providers must sign an attestation confirming receipt of the funds and agreeing to the terms and conditions of payment.

# CMS Waivers

Overview:

<https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>

Physicians and other clinicians:

<file:///C:/Users/bmilligan/Downloads/IFC2%20Physicians%20and%20Other%20Clinicians-FINAL508.pdf>

# Selected CMS waivers

For the duration of the Emergency Declaration.

- Facilitate hiring of physicians, nurses, and other clinicians to be readily hired from the community or from other states;
- Expand hospital capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls);
- Increase telehealth access for Medicare members;
- Expand in-place testing to allow for more testing at home or in community based settings;
- Provide temporary relief from many paperwork, reporting and audit requirements.

# Telehealth

- Physicians can provide telehealth services to patients regardless of patient location;
- New or established patients;
- Copay waivers are allowed (for telehealth and in-person);
- Audio-only technology permitted;

- Expansion of the types of services that can be provided;
- Reimbursement as if face-to-face;
- Elimination of frequency requirements; and
- Physicians are permitted to provide required supervision by telehealth.

# COVID Testing

- Medicare will pay physicians for assessment and specimen collection using the level 99211, for new and established patients.
- Medicare will not require an order from a provider as a condition of Medicare coverage of testing for COVID-19 or an influenza virus test and any other test necessary to establish or rule out a COVID-19 diagnosis

# “Patients over Paperwork”

- Waivers of certain Stark law requirements;
- Loosening of LCD and NCD coverage requirements;
- Waiver of signature requirements for Part B and DME;
- Changes to Merit-based Incentive Payment System; and
- Expanded and expedited Accelerated and Advance Payments
  - Being reevaluated;
  - Suspended in light of PRF payments

# HIPAA-Telehealth

<https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>

- DHHS Office for Civil Rights “will not impose penalties for noncompliance with HIPAA rules in connection with “the good faith provision of telehealth during the COVID-19 nationwide public health emergency.”
- Providers can use “any non-public facing remote communication product ... to communicate with patients, regardless of whether the telehealth service is related to ... COVID-19.”

# HIPAA - Telehealth

- “[P]roviders may use popular applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype, to provide telehealth without risk that OCR might seek to impose a penalty for noncompliance with the HIPAA Rules related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency.”

# HIPAA - Telehealth

- Providers are encouraged to notify patients that these applications may increase privacy risks, and providers should enable all encryption and privacy modes .
- OCR will not impose penalties against providers for:
  - Failing to have a BAA in place with video communication vendors or for
  - Any other good faith noncompliance with HIPAA that relates to telehealth services.

# HIPAA – Testing Sites

<https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-community-based-testing-sites.pdf>

- OCR will not impose penalties for violations of the HIPAA Rules ... in connection with the good faith participation in the operation of COVID-19 testing sites.
- The waiver is intended to support Community Based Testing Sites, including mobile, drive through and walk-up sites that only provide COVID specimen collection or testing services.

# HIPAA – Permissible Uses

<https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf>

This document is just a reminder of the permissible uses and disclosures of PHI, i.e., for:

- Use or disclosure for treatment;
- Disclosure to public health authorities;
- Certain disclosures to family members;
- Disclosure to prevent a serious, imminent threat,

All of which are subject to the “minimum necessary” limitation.

# Families First Coronavirus Response Act

- <https://www.dol.gov/agencies/whd/pandemic/ffcra-questions>
- Mandatory sick leave benefits for employees.
- Expansion of Family Medical Leave Act.
- Both apply to leave taken between April 1 and December 31, 2020.

# HR Issues: The Families First Coronavirus Response Act

- Department of Labor Notice regarding Sick Leave:  
<https://www.dol.gov/agencies/whd/pandemic/ffcra-questions>
- Employers with fewer than 500 employees must provide certain paid sick leave benefits to employees who are unable to work/telework because of the following COVID issues:

# Conditions Mandating Sick Leave

- A government quarantine or isolation order related to COVID-19;
- A provider's advice to self-quarantine due to COVID-19;
- Symptoms, and seeking a diagnosis;
- Caring for an individual who is subject to the above;
- Caring for a child if school is closed or day care is unavailable; or
- Any other substantially similar condition specified by DHHS, DOT or DOL.

# FFCRA Sick Leave Benefits

- Hours:
  - Full-time employees: 80 hours, immediately available.
  - Part-time employees: equivalent to two weeks normal work hours.
- Rate of pay:
  - Care for self: greater of normal rate of pay or minimum wage - capped at \$511/day and \$5,110 in the aggregate.
  - Care for others: greater of two-thirds of normal rate of pay or minimum wage - capped at \$200/day and \$2,000 in the aggregate.
- PTO: An employer cannot require an employee to use vacation or other paid time off before using paid sick leave.

# FFCRA Sick Leave

- Employers of healthcare workers and/or emergency responders may exclude those employees from paid sick leave provisions.
- Exemption:
  - DOL is authorized to exempt businesses with fewer than 50 employees if the requirements would jeopardize the “viability of the business”
  - exemption only applies to paid leave related to school closures/childcare unavailability.
- Employers must post a notice in a conspicuous place. DOL form notice available on line.
- Prohibition against discrimination based on sick leave, and potential fines.

# FFCRA Emergency FMLA

- Unlike FMLA,
  - EFMLA applies to employers with less than 50 employees, i.e., smaller practices,
  - Paid leave after ten days of leave, and
  - There is no 12-month/1,250-hour qualification requirement.
- Eligible employees: any full-time or part-time employee who has been on the job for at least 30 days.
- Amount of leave: up to 12 weeks.

# EFMLA

- Employees may use emergency leave when they are unable to work (or telework) because they need to care for a minor child whose school/daycare is closed or because the child's childcare provider is unavailable due to the COVID-19 outbreak.
- Payment:
  - Employer may designate the first ten days of emergency leave as unpaid (although an employee can opt to use FFCRA sick leave, vacation time or other paid time off for those days).
  - Beyond the first ten days, leave is paid at two-thirds of the employee's normal rate of pay with a cap of \$200/day and \$12,000 in the aggregate.

# EFMLA

- Upon return from leave, employees are entitled to return to the same or an equivalent position.
  - Possible exception if the employer has fewer than 25 employees, and the position does not exist due to changes on operating conditions due to COVID-19.
- Exceptions:
  - DOL is authorized to exempt businesses with fewer than 50 employees if leave requirements would jeopardize the “viability of the business.”
  - Employers of healthcare workers and/or emergency responders may exclude those employees from emergency leave provisions.

# DES unemployment benefits

## DES COVID Q&A

<https://des.az.gov/services/employment/unemployment-individual/covid-19-ui-qa>

- Relaxed requirements, e.g., independent contractor eligibility, no requirement to actively seek employment, suspension of the one week waiting period, possible benefits for reduced work hours.

# FFCA unemployment benefits

<https://www.dol.gov/coronavirus/unemployment-insurance>

- The Federal Pandemic Unemployment Compensation program provides an additional \$600 per week to individuals who are collecting regular UC.
- States are permitted to extend unemployment benefits by up to 13 weeks.
- Possible benefits for “primary care givers” who are required to work from home.
- Benefits end upon an offer of “suitable employment.”

# Closing a practice

- Things to do now.
- Things to do when you are getting ready to close.
- Closing vs sale.



# Closing a practice: Things to do now

Make sure your records retention practices are compliant:

- ARS 12-2297:
  - Adult patient: six years
  - “Child” patient: the later of six years or three years after 18yoa.
  - Upon retirement or sale, take “reasonable measures to comply.
- Payor requirements and risk management.
  - Federal FCA exposure could exceed 6 years.

# Things to do now

## ARS 32-3211: Medical Records Protocol

- All HCP, including physicians, must have a “written protocol for the secure storage, transfer and access of the medical records of the health professional's patients, including processes for:
  - Storage, etc. upon retirement or sale;
  - Disposition of unclaimed records; and
  - Responding to patient requests.
- Failure to have a written protocol is an act of unprofessional conduct.

# Closing vs sale

One possible consequence of the pandemic is that hospitals, insurers and private equity will step up their purchases of physician practices, so consider whether someone might want to buy your practice.



# Sample closing checklist

- Notify patients
- Records storage
  - Patient records –
    - EMR issues
    - Retention issues
    - Transfer issues
  - Business and billing
- Terminate
  - Payor contracts
  - Service contracts
- Building and equipment leases
- FF&E sale or disposal
- P/L Coverage
  - Tail, if retire, etc.
  - Change of practice
- License surrender?
- Drug disposal
- Billing and collection
- Pay creditors and dissolve entity
- Employees
  - Contracts?
  - WARN ( $\geq$  100 FTE)
  - Benefits contributions

# Takeaways

- Check the links to sites that may be relevant to your situation.
- Check government sites, including the following, on a regular basis: Governor Ducey; Arizona Department of Health Services; CMS; DHHS OCR; Treasury Department; SBA
- Remember, many of the rule changes will lapse when the National Emergency and Public Health Emergency declarations end,
  - But some, e.g., FFCRA, will not.

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