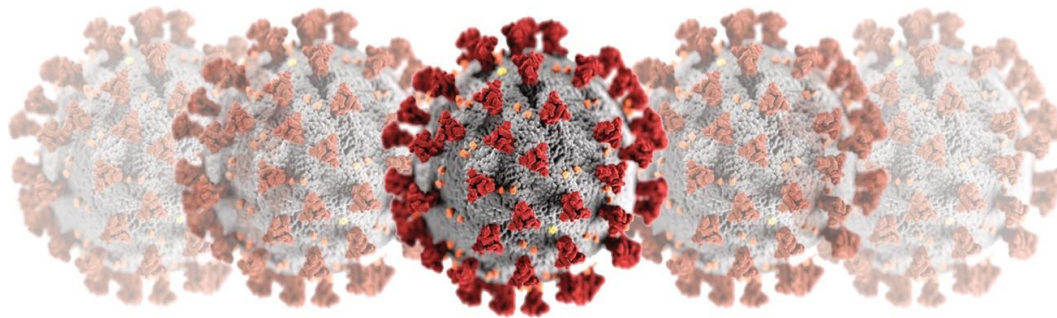


STATE BAR OF MONTANA

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HCLS: Flexibilities in Response to COVID-19

Responding to a Pandemic



Presented by
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Caution

These slides were prepared on May 27, 2020. They are intended to provide talking points. During this public health emergency rules, guidance and waivers are frequently changing – nearly on a daily basis. What was the law yesterday, may not be the law today. Please use caution when referencing these slides as the law or related guidance may have changed.



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Overview

- 2020: A Year to Remember
- What We've Learned
- Societal Response
- National and State Impact
- Government Response
- Overview of Various Waivers, Flexibilities and Guidance
- Miscellaneous thoughts on Practical Action Steps

2020: A Year to Remember

- Pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
- More than 100,426 U.S. deaths / 1.7M+ cases
- 40M+ unemployment claims
- Once a generation experience
- Sweeping legislative response
- Social, cultural, economic and health care norms are being reshaped
- The health care industry has a lot to learn




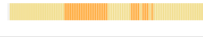






What Have We Learned?

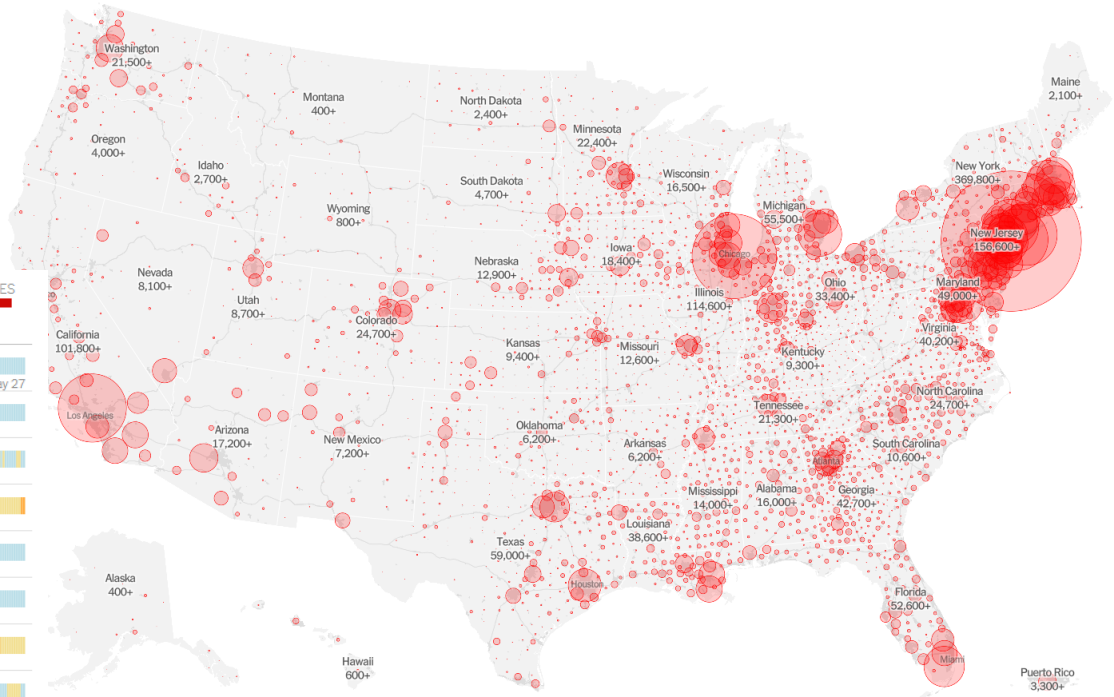
- Population health is difficult, especially when it affronts wide-held views re civil liberties
- There was a time that working from home sounded like a great idea
- You are a better or worse cook than you thought
- We have a national fascination with tigers and backyard zoos
- You likely now know a lot about Zoom and TikTok
- Good internet service is your most vital utility
- People will respond to the call

Societal Response

- Staying home
- Social distancing
- Working from home
- Shopping from home
- Personal actions (hoarding, safety-focused, etc.)
- Virtual interactions
- Adherence (and non-adherence) to government orders or recommendations
- Polarizing

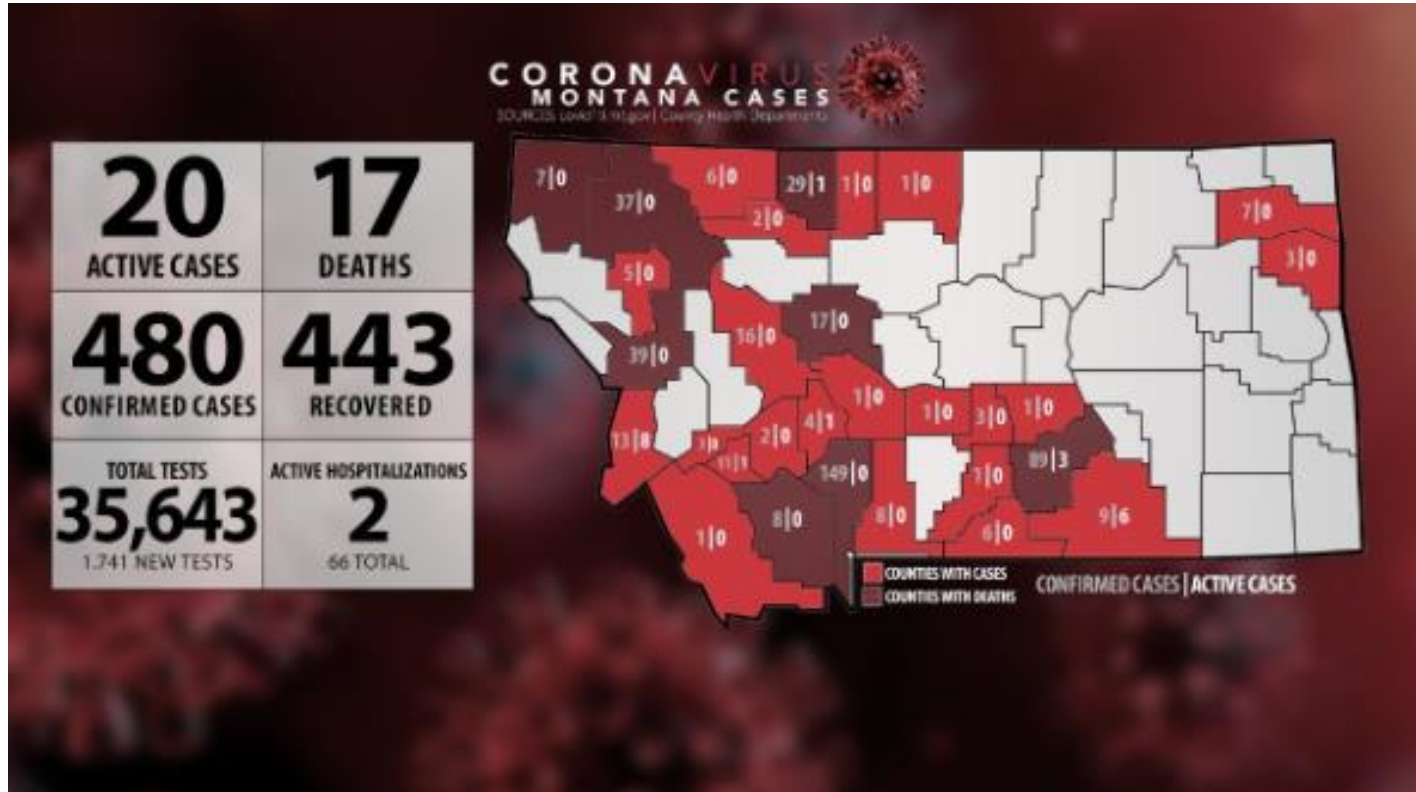
Wide Angle Lens

	▼ CASES	PER 100,000	DEATHS	PER 100,000	TWO-WEEK CHANGE IN CASES
					FALLING FLAT RISING
+ New York MAP »	369,801	1,901	29,339	151	
+ New Jersey MAP »	156,628	1,763	11,339	128	
+ Illinois MAP »	114,612	904	5,118	40	
+ California MAP »	101,874	258	3,961	10	
+ Massachusetts MAP »	94,220	1,367	6,547	95	
+ Pennsylvania MAP »	73,646	575	5,290	41	
+ Texas MAP »	59,047	204	1,598	6	
+ Michigan MAP »	55,544	556	5,334	53	
+ Florida MAP »	52,626	245	2,318	11	
+ Maryland MAP »	49,042	811	2,392	40	



Source: NYT

Status in Montana (as of May 27)



COVID-19 Impact on Health Care Industry

- The healthcare industry was already exceedingly complicated
 - Not just a business
 - Emotional and personal
 - Highly regulated
 - Expensive – nearly 18% of GDP at \$3.6T/year (budget sensitive)
 - Evolving rapidly
 - Exceedingly integrated
- Now add in **pandemic** to an already strained system
- “...the fight against this virus has created the greatest financial crisis in history for hospitals and health systems,” - Rick Pollack, AHA president

Local Impact?

- Number of positive cases and deaths tell very little
- Impact, experience and consequences are relative
- Remember, healthcare is highly integrated
- Cost (direct and opportunity), time, resources, leadership
 - Being prepared is vital (from standard of care to liability)
- Bans or limitations on elective procedures have a sweeping impact
- The relationship between community concern and ER visits

Overarching Government Response

- Subsidies
- Additional Payments / Grants
- Loans
- Tax Credits
- Expanded Funding and Coverage of Services
- Healthcare program waivers
- Public Health Guardrails (FDA, OSHA, CDC, and local public health agency recommendations)
- Wage and Hour Guidance from EEOC, DOL, and state counterparts
- Individual Economic Assistance

Healthcare-oriented

- Federal agencies' response: In the hundreds, literally
- Medicare FFS flexibilities from CMS
- Blanket waivers and flexibilities related to telemedicine
- Stark Law blanket waiver
- Statutory response
- Regulatory changes
- Guidance issued by:
 - CMS, OIG, DEA, FDA, HHS sub-agencies, FEMA, IRS, DOL, and various accrediting agencies

The 1135 Focus

Providers

- Critical Access Hospitals
- Acute Care Hospitals
- Skilled Nursing Facilities (SNFs)
- Inpatient Psychiatric Services
- Inpatient Rehabilitation Services
- Long-Term Care Acute Hospitals
- Home Health Agencies
- Hospice
- Physicians and APPs
- Laboratories
- And more...

Scope

- Conditions of Participation and various program participation requirements
- Physician licensure
- EMTALA
- Stark Law
- HIPAA
- Telehealth

Beyond Waivers and Flexibilities: CMS

- Interim Final Rule and Temporary Rules
- Guidance
 - Waiver interpretation
 - Inspections
 - Infection control
 - Coverage and benefits
 - EMTALA
 - Program changes
 - Claims processing
 - And more

Beyond CMS: OIG*

- Minimizing Burdens on Providers
- Policy Statement Regarding Application of Certain Administrative Enforcement Authorities
- National Pulse Survey

*Select
examples

Beyond CMS: DEA*

- Methadone Shortages
- Questions and Answers for Registration of Emergency Temporary Sites and Picking Up Controlled Substances Orders from Distributors
- Registrant Guidance on Controlled Substance Prescription Refills
- Exception to Separate Registration Requirements Across State Lines

Beyond CMS: FDA*

- FAQs on Diagnostic Testing for SARS-CoV-2
- Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Temporary Policy Regarding Non-Standard PPE Practices for Sterile

Beyond CMS: CDC, FEMA, OCR, etc.*

- Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'
- CDC: COVID-19 Testing and Reporting by Laboratories: Q & A
- CDC Training for Healthcare Professionals
- CDC: Multisystem Inflammatory Syndrome in Children (MIS-C) Associated with COVID-19
- FEMA: Coronavirus Emergency Management Best Practices
- HHS/OCR: Coronavirus Emergency Management Best Practices
- 18 • SAMHSA: Letter to Treatment Providers on PPE

Beyond CMS: IRS*

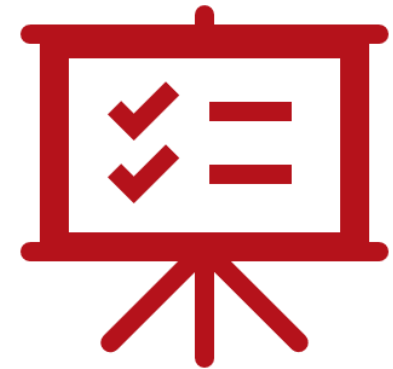
- FAQ: Nonresident aliens and foreign businesses impacted by COVID-19 travel disruptions
- Notice 2020-15: High Deductible Health Plans and Expense Related to COVID-19
- Notice 2020-18 – Tax Day Extended to July 15
- Notice 2020-22 – Relief from Penalty for Failure to Deposit Employment Taxes
- IR-2020-59 – New People First Initiative

Beyond CMS: DOL*

- Guidance on Preparing Workplaces for COVID-19
- What You Should Know About the ADA, the Rehabilitation Act and the Coronavirus
- What You Should Know About the ADA, the Rehabilitation Act and the Coronavirus
- Interim Enforcement Response Plan for Coronavirus Disease 2019 (COVID-19) (Updated 5/19/20)

So - What to Do Next?

- Who? Reflect on your mission
- What? Balance known, likely and possible needs - envision a new marketplace; When? What changed and what have you learned?
- When? What has happened and what is trending?
- Where? The challenge of identifying priorities
- How? - Develop action steps
 - Prioritize initiatives
 - Engage your workforce
 - Activate /deploy solutions



Being Compliant *or* Being Flexible?

- An effective pandemic response requires flexibility, agility and access to resources (and good judgment)
- It is an understatement to refer to the healthcare industry as highly regulated – with oversight and enforcement at all levels
- A “compliance” mindset is in our DNA
- How is a highly regulated health care provider able to effectively adapt to what a pandemic demands?
- Bylaws/Policies/Practices are not the law, but they play one on TV
- Knowing when you can, can’t and shouldn’t “color outside the lines” is a skill

Being Compliant *or* Being Flexible, cont.

- The lines are not so bright:
 - Federal guidance – 1135 waivers, non-regulatory guidance, clarity
 - State guidance – Licensing Boards and Facility-licensing Authorities
 - Consistency in state actions, e.g., licensing flexibility

Misc. Practical Action Steps

- Finance
- Physician / Provider Alignment
- Patient and Operational Care Delivery
- Risk Management
- Business Intelligence and Planning
- Policies 2.0
- Leadership Development
- Practitioner Health
- Work-ups

Finance

- Execute on all government funding and payment options
 - \$100B Funding Relief, SBA Programs, Grants
 - Assess all compliant reimbursement opportunities (e.g., provider-based)
- Examine payer matters and clinical integration opportunities
 - Identify and get ahead of payer and managed care contract issues (e.g., provider licensing, personnel credentialing)
 - Understand payment options with care delivery changes

Physician / Provider Alignment

- Effectively and financially align all physicians, APPS, and other providers
 - Employed compensation strategy implementation
 - Independent physician arrangements and alignment execution
 - Examine futuristic value of various models for needed and changed service lines
- Proper business plan, models and formulas, **communications** and **intent** necessary in light of Anti-Kickback and Stark Law

Patient Care Delivery

- Effective communication strategy
- Advance available virtual care initiatives
 - Understand new opportunities and reimbursement (e.g. telemedicine and remote home care monitoring, etc.)
 - Establish proper and legal alignment with physicians and providers
 - Understand multi-state initiatives and quality reviews
- Continue to develop behavioral health solutions
- Implement needed post-acute relationships for patients

Operational Care Delivery

- Establish a modernized supply chain
 - Contemporary contracts with vendors for shared savings and proper materials
 - Understand FDA/life sciences impacts and pharmaceuticals options
- Be prepared for non-COVID patient surges and operations
 - Workforce licensure, training, applicable materials
 - New care delivery guidelines for social distancing workplace

Risk Management

- Understand and prepare strategy for post-Covid litigation
 - Whistleblower/False Claims Act, employment disputes, contract matters, business interruption insurance, service issues
- Enact an up-to-date compliance process
 - Understand federal/state changes and impacts
 - Implement targeted, pro-active audits to get ahead of whistleblowers

Documentation is Key

- We will be second guessed
- We will be sued
- Opportunists will seek opportunity
- Maintain documentation of thought process, reasoning, etc.

Business Intelligence and Planning

- Understand current legislative landscape and where your organization fits into the puzzle
 - Up-to-date monitoring of Washington, DC and Montana changes including a process for quick action steps
- Consider collaboration and consolidation opportunities
 - Evaluate continuum of care providers and suppliers in market area
 - Develop legal partnership models in light of antitrust rules
- Refine Strategic, Financial Budget, and Operational Plans

Bylaws/Policies/Protocols

- Did/do your bylaws, rules, policies address your needs?
- Do you need your own “1135” waivers?
 - Flexibility on responsibilities and duties
 - Flexibility on delegating authority
 - Flexibility on forming and use of ad hoc or subcommittees
 - FPPE/OPPE – QA/PI
 - Election/Appointment terms
 - Flexibility on qualifications; volume or patient activity requirements
 - Scope of urgent amendment authority?
 - Meeting management

Leadership Development

- Were/are your leaders, managers, supervisors prepared?
- Are they prepared to operate beyond “this is the way we’ve always done it”?
- Do they know and understand emergency preparedness or crisis communication?
- Consider adding a component to your Onboarding/Orientation programs (or maybe this is the nudge to get that off the ground)
- Consider focused training or education

Practitioner Health

- Practitioner health is never more important and their **value** never more appreciated
- This PHE is creating demands, stress, grief, perceived duty or futility, and so on - the likes of which we've not experienced
- Suicide
- Does your physician/practitioner wellness function work?
- Is now the time to prioritize the value of a comprehensive approach to practitioner well-being?

“Work-ups”: Practice Makes Perfect

- Were/are your practices and policies ready for battle?
- Was/is your staff ready for battle?
- Did you need to blow dust off of a policy?
- Did you have the necessary guidance?
- Do you stress test your policies?
- Does your organization leadership know how to integrate with your function on atypical issues?
- Is politics or your culture a hurdle?
- Professional development justification



Takeaways

- Prepare your post-apocalyptic communication plan now:
 - Expiration of waivers, flexibilities, privileging actions, etc.
- Keep a running list of what worked, didn't work, what fell apart, the questions you encountered
- Flag policies or practices that created confusion or were ineffective
- Be intentional about being flexible
- Anticipate legislation and regulation
- Plan a post-pandemic assessment with leadership and stakeholders



Please visit the Hall Render Blog at <http://blogs.hallrender.com> for more information on topics related to health care law.

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