

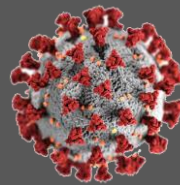


Medical Expertise for Healthcare Defense  
Claims | Litigation | Compliance

# THE COVID CHALLENGE

FRIENDS SERVICE ALLIANCE

SEPTEMBER 21, 2020





# AGENDA

- Introductions
- The Covid Landscape
- Defenses – Prep Act & Immunity Orders
- State and Federal Guidance
- Litigation Landscape
- Documentation Best Practices
- Our Solution
- Case Studies
- Question & Answer



# PRESENTERS



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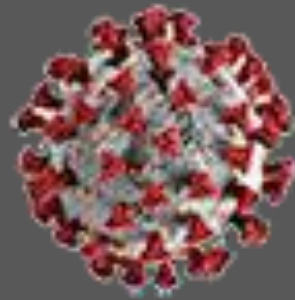


## QUESTIONS AND POLLING

- Any questions can be entered throughout the presentation in the chat
- Participant Surveys
  - Grab your phone or open a 2nd browser window and go to [menti.com](https://www.menti.com)
  - Type in the code shown on the top of the presentation
  - Vote! And the results will appear live on your screen

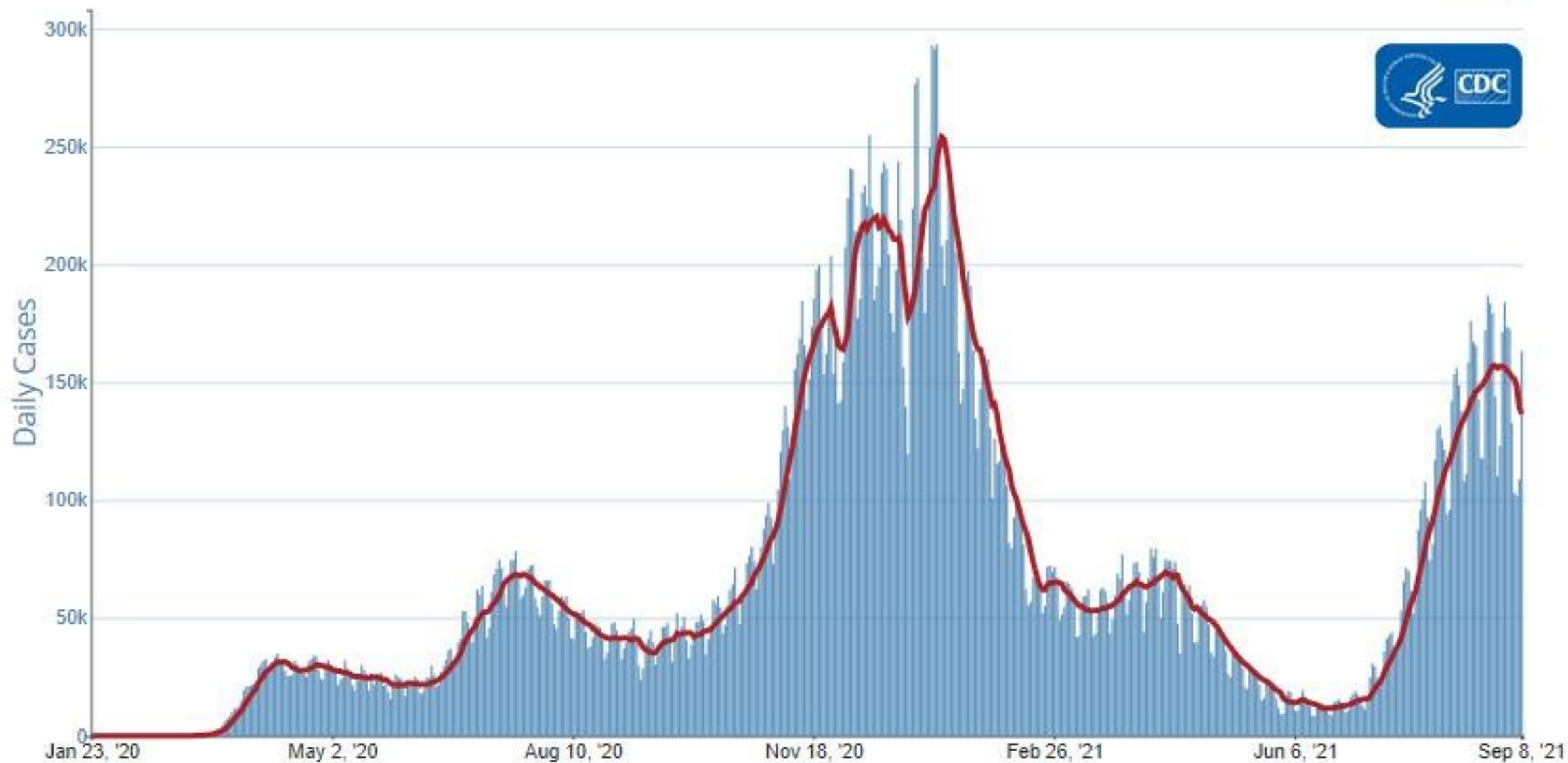


# COVID LANDSCAPE

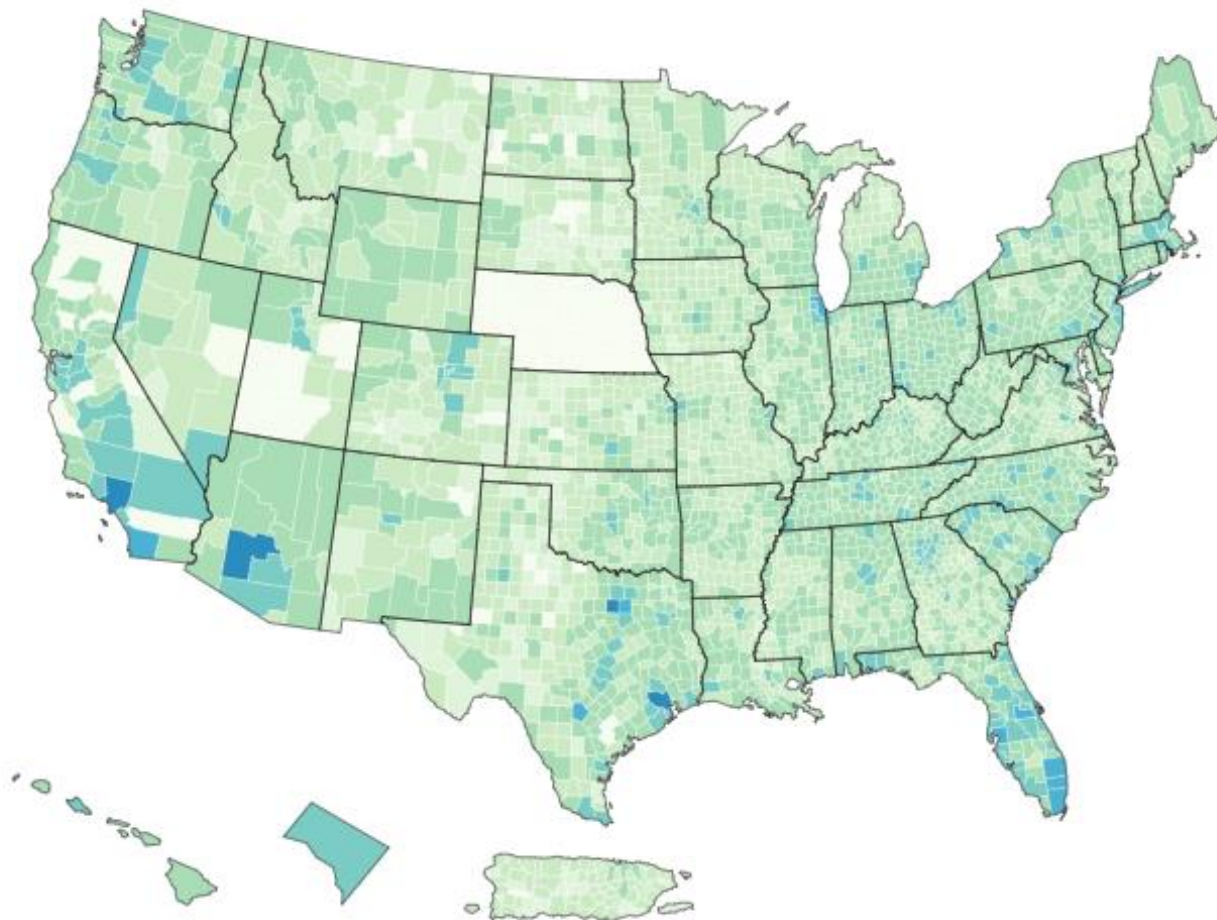


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# COVID CASES IN THE US



# COVID CASES BY STATE

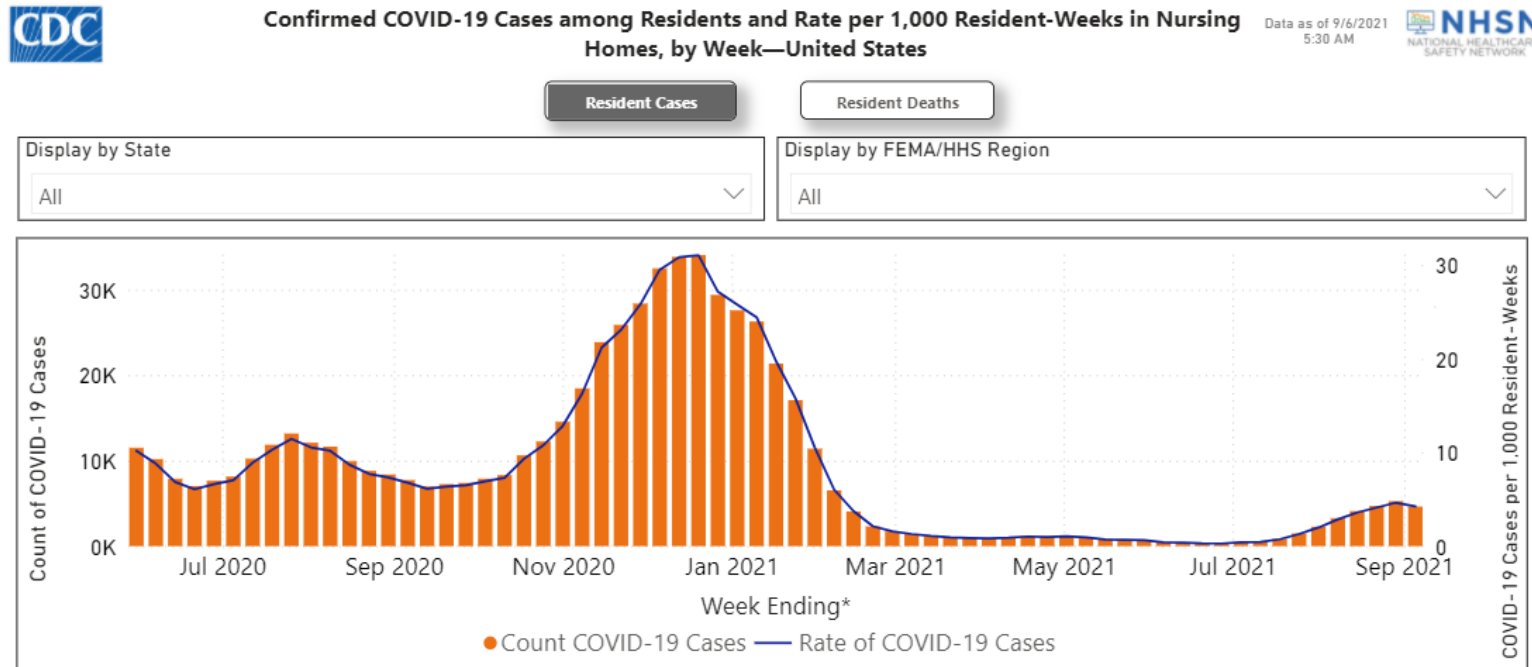


# COVID CASES – LTC FACILITIES



## Confirmed COVID-19 Cases and Deaths among Residents and Rate per 1,000 Resident-Weeks in Nursing Homes, by Week - United States

CDC's National Healthcare Safety Network (NHSN) is supporting the nation's COVID-19 response by providing a [Long-term Care Facilities \(LTCFs\) COVID-19 Module](#), which enables an assessment of the impact of COVID-19 through facility reported information, including: counts of residents and facility personnel (staff) with positive COVID-19 viral test results and death counts among residents and facility personnel with positive COVID-19 viral test results. Read more about the data at: [Nursing Home Covid-19 Data Dashboard](#)

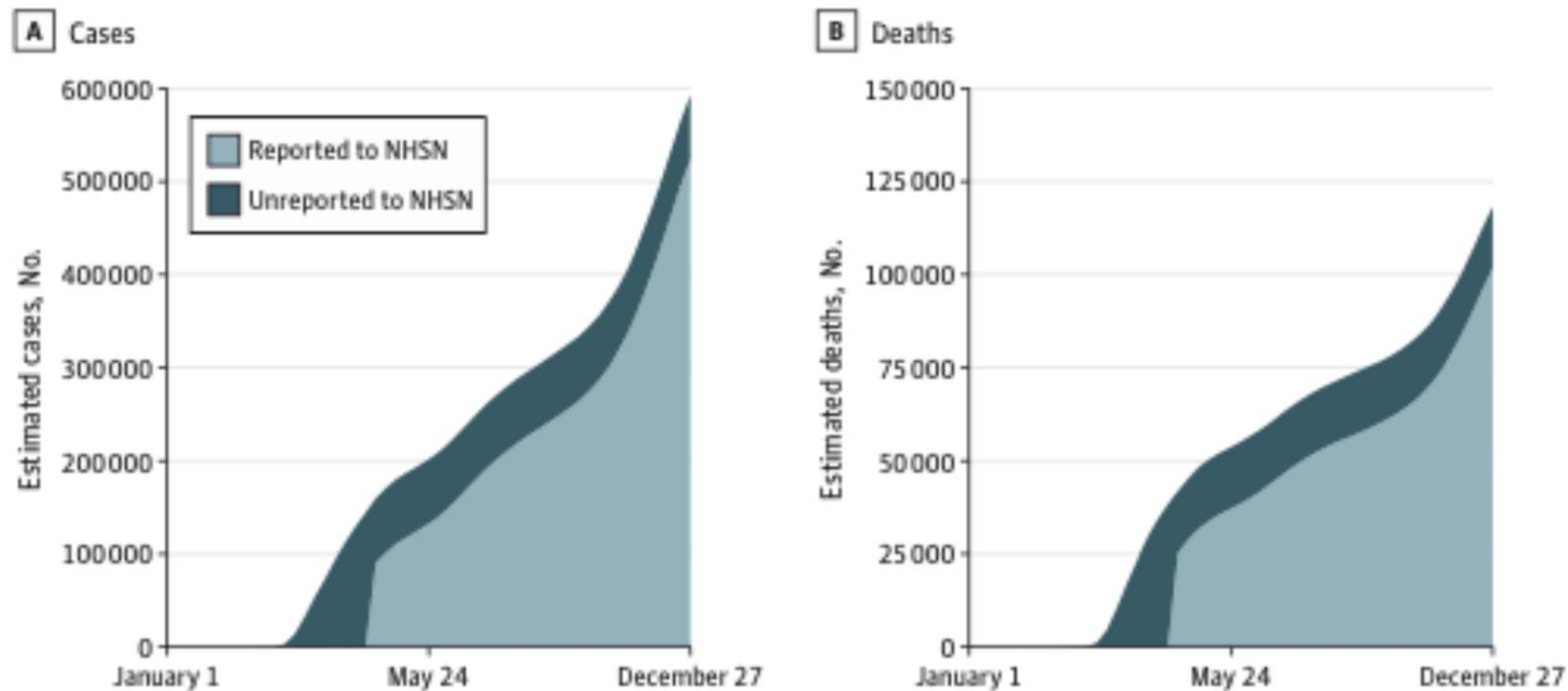


\* Data are likely accruing, all data can be modified from week-to-week by facilities

For the purpose of creating this time-series graph, data that fail certain quality checks or appear inconsistent with surveillance protocols are assigned a value based on their patterns for data-entry or excluded from analysis



**Figure 4. Estimated and Reported National Cumulative Cases and Deaths in Nursing Homes**



# COVID CASES – AMONG LTC STAFF



## Confirmed COVID-19 Cases and Deaths among Staff and Rate per 1,000 Resident-Weeks in Nursing Homes, by Week - United States

CDC's National Healthcare Safety Network (NHSN) is supporting the nation's COVID-19 response by providing a [Long-term Care Facilities \(LTCFs\) COVID-19 Module](#), which enables an assessment of the impact of COVID-19 through facility reported information, including: counts of residents and facility personnel (staff) with positive COVID-19 viral test results and death counts among residents and facility personnel with positive COVID-19 viral test results. Read more about the data at: [Nursing Home Covid-19 Data Dashboard](#)



### Confirmed COVID-19 Cases among Staff and Rate per 1,000 Resident-Weeks in Nursing Homes, by Week—United States

Data as of 9/6/2021  
5:30 AM



Staff Cases

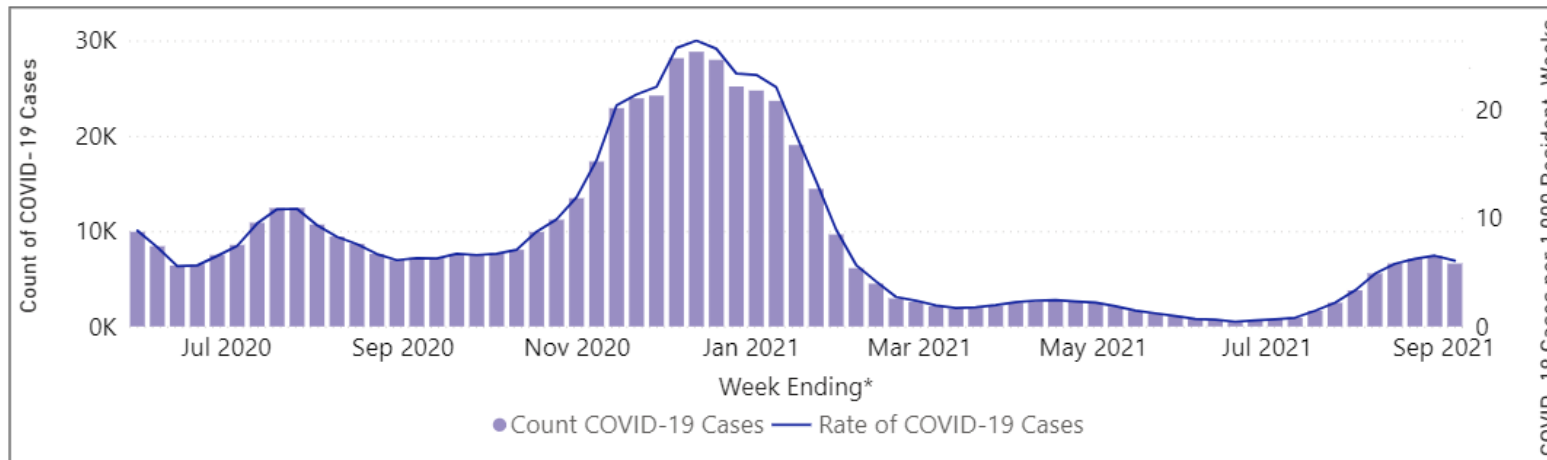
Staff Deaths

Display by State

All

Display by FEMA/HHS Region

All



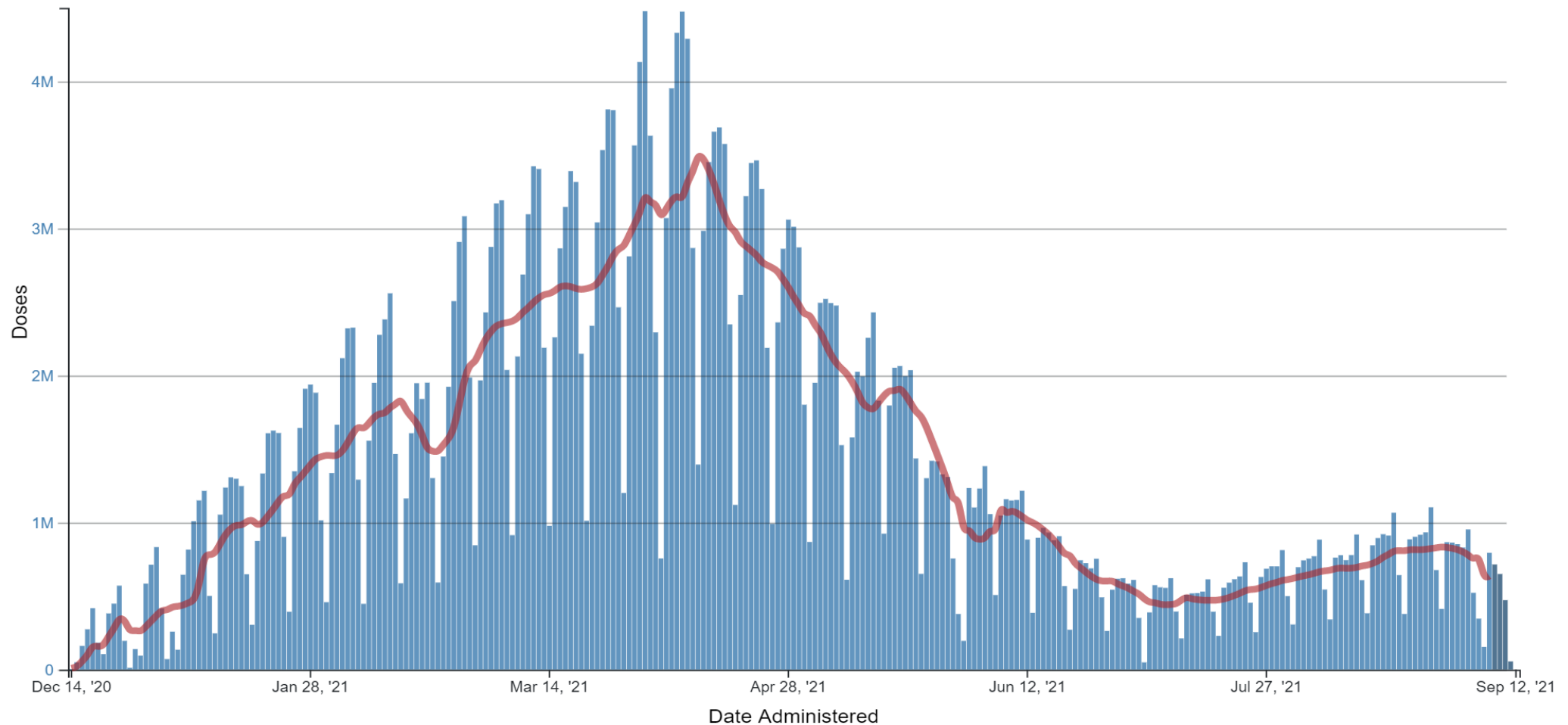
\* Data are likely accruing, all data can be modified from week-to-week by facilities

For the purpose of creating this time-series graph, data that fail certain quality checks or appear inconsistent with surveillance protocols are assigned a value based on their patterns for data-entry or excluded from analysis

# COVID-19 VACCINATION DATA - CMS



Daily Count of Total Doses Administered and Reported to CDC by Date Administered, United States



# COVID-19 VACCINATION TRENDS AND CMS MANDATES

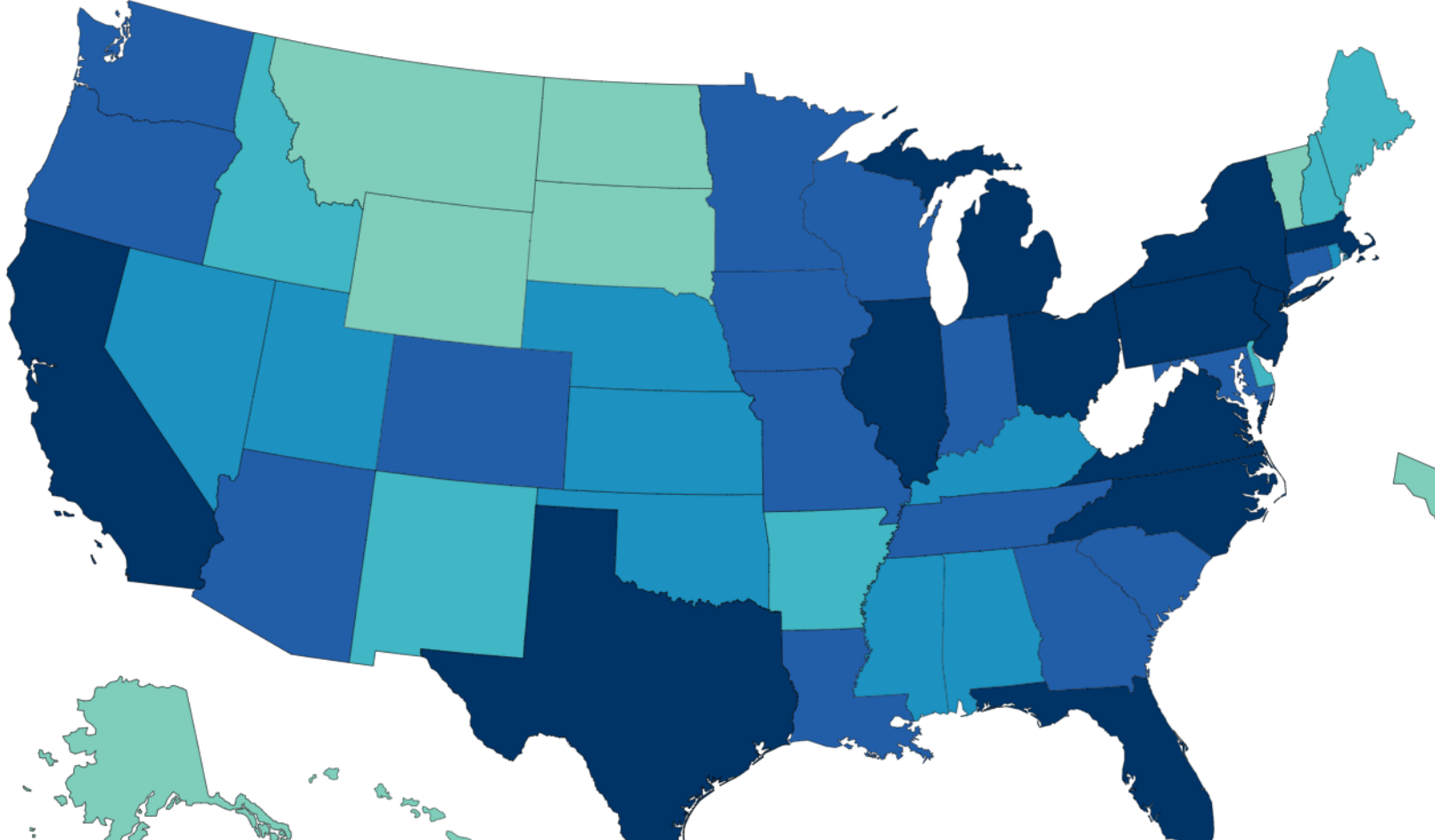


- May 2021: New regulations regarding education for residents, clients, and staff. Weekly reporting of COVID-19 vaccination data for residents and staff to the CDC
- August 8, 2021: Nationally 62% of nursing home staff are currently vaccinated and vaccination among staff at the state level ranges from a high of 88% to a low of 44%
- August 18, 2021: CMS in collaboration with the CDC, developed an emergency regulation requiring staff vaccinations for more than 15,000 Medicare and Medicaid-participating nursing homes
- September 9, 2021: Vaccines mandated for all private-sector employees, health care workers and federal contractors

# VACCINATION STATUS BY STATE - LTC

This shows how many doses of vaccine have been given to residents and staff in long-term care facilities.

Total Doses Administered Reported to CDC by State/Territory, Federal Pharmacy Partnership for LTC Program



# STRATEGY

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## POLL QUESTION

Do you have any involvement within your healthcare organization for the response to COVID-19 directives? (ex. member of a Covid task force)



# PREPARATION AND ORGANIZATION







## POLL QUESTION

Are you familiar with the PREP Act and/or your state's Immunity Orders?



# PREP ACT & IMMUNITY ORDERS

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# PUBLIC READINESS & EMERGENCY PREPAREDNESS ACT



- Enacted by congress in 2005
- Authorizes the Secretary of the US Department of HHS to issue a declaration in response to a public health emergency
- Provides expansive immunities from liability to certain “covered persons” for taking certain “covered countermeasures” necessary to combat a public health emergency

# PUBLIC READINESS & EMERGENCY PREPAREDNESS ACT



## Covid-19

- March 17, 2020: Declaration by DHHS triggered PREP act protections retroactive to March 4, 2020
- March 24, 2020: DHHS Secretary sent letter to Governors calling for them to develop a list of state liability protections
- August 4, 2021 HHS Secretary issued 8<sup>th</sup> amendment – covering pharmacy technicians and interns to administer flu and covid vaccines / therapeutics
- September 14, 2021 – 9<sup>th</sup> amendment set to be published
- Liability protections extend through the final day of the Declaration of Emergency or October 1, 2024, whichever occurs first

# PUBLIC READINESS EMERGENCY PREPAREDNESS ACT



- Immunity includes:
  - Any claim, under federal or state law, for loss that has a causal relation with the administration to or use by an individual covered by a countermeasure
  - Loss includes: death, personal injury, emotion injury, property damage, business interruption and fear of personal injury
  - Protection is very broad and applies “without regard to the date of the occurrence, presentation or discovery of loss”
  - \*Does not cover willful misconduct



## EXAMPLE: IMMUNITY PROVIDED IN PENNSYLVANIA

- May 6, 2020
  - Governor Tom Wolf issued an Executive Order providing civil liability immunity to health care provider for good faith actions taken in response to the Covid-19 health emergency.
  - The order does not extend to care and treatment of non-Covid patients.
  - The order does not extend to Nursing Homes



## EXAMPLE: IMMUNITY PROVIDED IN PENNSYLVANIA

- November 20, 2020
  - House bill 1737 passed the Pennsylvania House and Senate.
  - Offers protections to long-term facilities and hospitals, from being held civilly liable from damages related to COVID-19 outcomes unless there's "clear and convincing evidence of gross negligence, recklessness, willful misconduct or intentional infliction of harm."



## EXAMPLE: IMMUNITY PROVIDED IN PENNSYLVANIA

- December 1, 2020
  - Governor Tom Wolf vetoed Bill 1737
  - Stating the legislation would undermine COVID-19 mitigation efforts and endanger public health.
  - Measure would have provided “broad, overreaching immunity from civil liability.”
  - “Shielding entities from liability in such a broad fashion as provided under this bill invites the potential for carelessness and a disregard for public safety,”





## EXAMPLE: IMMUNITY PROVIDED IN PENNSYLVANIA

- April 6, 2021
  - House of representatives bill to protect healthcare workers, businesses, health care facilities, nursing homes and schools
  - Falls short of blanket immunity and those covered will still have to follow all guidelines.
  - Pennsylvania Health Care Association supported bill
  - "Businesses that did their best to provide essential goods and services should not have to worry about costly litigation"

# COVID CIVIL LIABILITY BY STATE

Prepared by Wilson Elser  
July 2021

STATE	IMMUNITY	NURSING HOME IMMUNITY
Alabama	Yes	No
Alaska	Yes	No
Arizona	Yes	Yes
Arkansas	Yes	No
California	Yes	No
Colorado	No	No
Connecticut	Yes	Yes
Delaware	Yes	Yes
District of Columbia	Yes	Yes
Florida	Yes	Yes
Georgia	Yes	Yes
Hawaii	Yes	Yes
Idaho	Yes	Yes
Illinois	Yes	Yes
Indiana	Yes	Yes
Iowa	No	No
Kansas	Yes	Yes
Kentucky	Yes	Yes
Louisiana	Yes	Yes
Maine	No	No
Maryland	Yes	Yes
Massachusetts	Yes	Yes
Michigan	Yes	Yes
Minnesota	No	No
Mississippi	Yes	Yes
Missouri	Yes	Yes

STATE	IMMUNITY	NURSING HOME IMMUNITY
Montana	Yes	No
Nebraska	Yes	Yes
Nevada	Yes	No
New Hampshire	Yes	Yes
New Jersey	Yes	Yes
New Mexico	No	No
New York	Yes/No	Yes/No
North Carolina	Yes	Yes
North Dakota	Yes	Yes
Ohio	Yes	No
Oklahoma	Yes	Yes
Oregon	No	No
Pennsylvania	Yes	No
Rhode Island	Yes	Yes
South Carolina	Yes	No
South Dakota	Yes	Yes
Tennessee	Yes	Yes
Texas	Yes	Yes
Utah	Yes	Yes
Vermont	Yes	Yes
Virginia	Yes	Yes
Washington	Yes	No
West Virginia	Yes	Yes
Wisconsin	Yes	Yes
Wyoming	Yes	Yes

# STATE & FEDERAL GUIDANCE

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## POLL QUESTION

Is your health care organization collecting & archiving COVID-19 Guidance from the state or federal agencies?

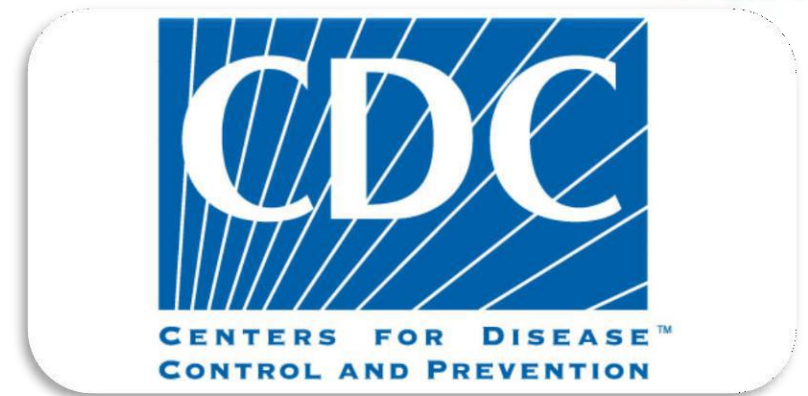
How is your organization archiving information?



# COVID GUIDANCE - AGENCIES



## Federal Guidance



## State Guidance



## Local Guidance



# GUIDANCE / DIRECTIVES

- Every aspect of facility operations
  - Screening
  - Testing
  - Cleaning
  - Education
  - Visitation
  - Dining
  - Services
  - Activities
  - Source control
  - Vaccinations



# COVID GUIDANCE – FEDERAL - CDC



- Guidance for Monitoring Exposed or COVID-19 Positive Patients
- Preparedness Checklists for Transport & Arrival of Patients
- Guidance for Collecting, Handling, & Testing Clinical Specimens, Lab Biosafety Guidelines
- Clinical Guidance for COVID-19 Outbreak
- Risk Assessment; Cleaning, Disinfecting, & Decontamination Protocols
- Higher Risk for Severe Illness with Comorbid Conditions
- Infection Prevention & Control Recommendations
- Updates to How the Virus is Spread
- Clinical Screening Recommendations, Symptoms Updates, Isolation/Quarantine Precautions, Visitor Screening Guidance





# COVID GUIDANCE – FEDERAL - CDC

- Reporting Requirements
- Postmortem Guidance, Guidance for Certifying Deaths
- Return to Work Criteria
- Optimization of PPE, PPE Guidance, PPE Burn Rate Calculator
- Evaluation and Testing Recommendations
- Recommendation on Vaccines (Storage/Temperature logs, Standing Orders, Preparation and Administration Summaries)
- Mass Gathering/Social Distancing Recommendations
- Initiating Case Investigation and Contact Tracing Activities





# COVID GUIDANCE – FEDERAL - CMS



- Emergency Preparedness Rules
- Health System Expansion Guidance
- Telehealth Recommendations
- Waivers (acting in good faith; not subjected to sanctions for noncompliance)
- Infection Control & Prevention Updates
- Transportation Guidelines
- Testing Requirements
- Mask Guidance, Visitation Recommendations
- Elective Surgery Recommendations
- Reporting Requirements
- Background Check Regulatory Requirements
- Reopening Guidelines
- Prioritization of Survey Activities
- Pricing Transparency Requirements



# COVID GUIDANCE – FEDERAL - FDA



- Emergency Use Authorizations for drugs to treat, PPE, Decontamination Kits, Sterilization Systems, Testing Kits, Vaccine
- Recommendation for Medical Gowns, Gloves, Respirators/Vents, Hand Sanitizers
- Enforcement Policies for Sterilizers, Disinfectants, Air Purifiers, Thermometers, Face Shields, Surgical Masks
- Conservation Strategies for PPE
- Fact Sheet for Healthcare Providers for medications approve for treatment
- Storage Recommendations for Vaccines
- Drug Shortage Responses



# COVID GUIDANCE – FEDERAL – Department of Health & Human Services



- Declaration of Public Health Emergency
- PREP Act & CARES Act Clarifications
- Authorizing Licensed Professionals to perform duties not normally done
- Hoarding Prevention Measures, Optimizing PPE
- Guidance for Certifying Deaths
- Laboratory Data Reporting Guidance
- Uninsured Program
- Operation Warp Speed-accelerating therapeutic development/Vaccine Plan



# COVID GUIDANCE – FEDERAL – White House



- National Guard Assistance
- Executive Orders
- Guidance on Interpreting COVID-19 Test Results
- Emergency Aid Bills
- Plans to Reopen Country
- National Testing Strategy
- Operation Warp Speed
- Vaccine Allocation Plan



# COVID GUIDANCE – FEDERAL – Office of Civil Rights



- HIPAA Disclosure Recommendations, Telehealth Recommendations
- Guidance for Covered Health Care Providers, Restrictions on Media Access



# COVID GUIDANCE – FEDERAL – National Institutes of Health

- Clinical Trials Updates
- Medication Regimen Recommendations
- COVID-19 Treatment Guidelines



# COVID GUIDANCE – FEDERAL – Occupational Safety and Health Association



- Guidelines on Keeping Workers Safe During Pandemic, Social Distancing
- Infection Control & Prevention for Exposure for Healthcare Workers
- Enforcement Guides for Respirators & Decontamination
- Enforcement Guide on Recording Cases
- Postmortem Care for Workers



# COVID GUIDANCE – FEDERAL – Federal Emergency Management Agency

- Pandemic Response Recommendations
- Emergency Protective Measures
- Pandemic Supply Chain Stabilization, PPE Delivery



FEMA



# COVID GUIDANCE – FEDERAL – United States Department of Labor



- Families First Coronavirus Response Act Employee Paid Leave Rights
- Guidance for Unemployment
- Reopening Guidance & Worker Safety



# COVID GUIDANCE – FEDERAL – American Medical Association/American Hospital Association

- COVID-19 Resource Guide for Physicians
- Standard of Care Guidance
- Liability Protections for Health Care Workers
- Code of Ethics Guidance
- Managing Mental Health During COVID-19
- Caring for Essential Workers
- Telemedicine Guidance
- Surgical Patient Guides
- Maintaining Trauma Center Access
- Vaccine Mandates



# COVID GUIDANCE – FEDERAL – World Health Organization



- Strategic Preparedness and Response Plan
- Laboratory Biosafety & Testing Guidance
- Case Management of COVID-19 in Health Care Facilities
- Monitoring & Evaluation Recommendations



# COVID GUIDANCE – **STATE** - Department of Health



- Guidance for Monitoring Exposure
- COVID-19 Detection and Reporting Requirements
- Transportation Requirements
- Clinical Guidance
- Infection Control Guidance
- Testing Guidance
- Specimen Collection, Packaging, & Shipping Guidance
- Laboratory Biosafety
- Visitation, Screening Guidance
- Vaccine Guidance and Enrollment



# COVID GUIDANCE – **STATE** – Department of Health



- Reporting Requirements
- Return to Work Criteria
- Face Coverings, Mass Gatherings, and Travel Recommendations
- Isolation/Quarantine Recommendations
- License Renewal Requirements for Healthcare Personnel



# COVID GUIDANCE – **STATE** – Medical Association



- Recommendations to Prevent the Spread of COVID-19
- Summaries of Executive and Emergency Orders
- Summaries of CMS Waivers
- License Reactivation of Healthcare Practitioners
- Reporting Requirements for Healthcare Providers



# COVID GUIDANCE – **STATE** – Hospital Association



- Post-Acute Care Facility Transfer Assessments
- Infection Transmission Prevention Precautions
- Guidance on Testing & Disposition of Hospitalized Patients
- Optimizing PPE Use, PPE Supplier List
- Staffing Resources
- Resource Lists for Hospitals



# COVID GUIDANCE – **STATE** – Governor Executive Orders, Emergency Orders, and Legislation



- Declaration of Public Health Emergency
- Stay at Home Orders
- Closures, Prohibiting Mass Gatherings
- Mask Mandates
- COVID-19 Response Protocols
- Telemedicine Expansion
- Extension of Professional Licenses, Recruitment of Retired Professionals
- Reopening Guidelines
- Immunity Orders





# COVID GUIDANCE – **STATE** – Health Care Association

- Emergency System Status for Hospital Providers
- Hospital Bed Emergency Status System
- Testing Requirements
- Hospital Screening Requirements
- Hospital Reporting Requirements
- Medicaid Waivers of Prior Authorization of Transfers
- Isolation/Quarantine Recommendations
- License extensions for Healthcare Personnel
- Vaccine Allocation



COMMUNITY  
HEALTH CARE  
ASSOCIATION  
of New York State  
[chcanys.org](http://chcanys.org)

# COVID GUIDANCE – **STATE** – Department of Aging, Elder Care Services



- Guidance on Training Programs
- Nutrition Service Updates
- Reporting Guidance
- Waiver Programs



**Additional CDC, CMS, White House, FEMA documents as related to state**

# COVID GUIDANCE – **STATE** – SNF or ALF



- Organizations included:
  - State Government Executive Orders, Emergency Orders, Legislation
  - Department of Health
  - Department of Aging, Elder Care Services
  - Health Care Association
  - Hospital Association
  - CDC & CMS as relates to specific state



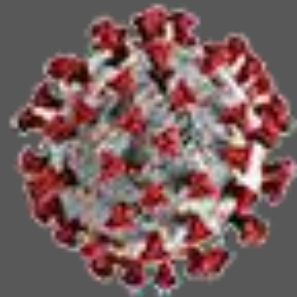
# COVID GUIDANCE – **LOCAL** – Department of Health



- Reporting Requirements
- Return to Work Criteria
- Face Coverings, Mass Gatherings, and Travel Recommendations
- Isolation/Quarantine Recommendations
- License Renewal Requirements for Healthcare Personnel



# LITIGATION LANDSCAPE



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# ANTICIPATING FUTURE COVID CLAIMS

- Failure to prevent / mitigate the spread of Covid-19
- Failure to recognize a change in condition related to Covid infection
- Failure to notify family and/or physician of Covid related issues
- Delay in treatment
- Failure to prevent asymptomatic workers from spreading the virus
- Inadequate staffing
- Inadequate or inappropriate use of PPE
- Negligent infection control practices
- Failure to follow local and/or federal guidance
- Negligent treatment of non-Covid patients including delays in treatments and/or surgeries



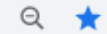
# CLAIM / LITIGATION LANDSCAPE

- Key Time Period
  - Originally March 2020 – October 2020
  - Now this time period has been extended with new guidance ...
- COVID-19 not directly mentioned in a claim or letter of intent

# COVID-19 COMPLAINT TRACKER



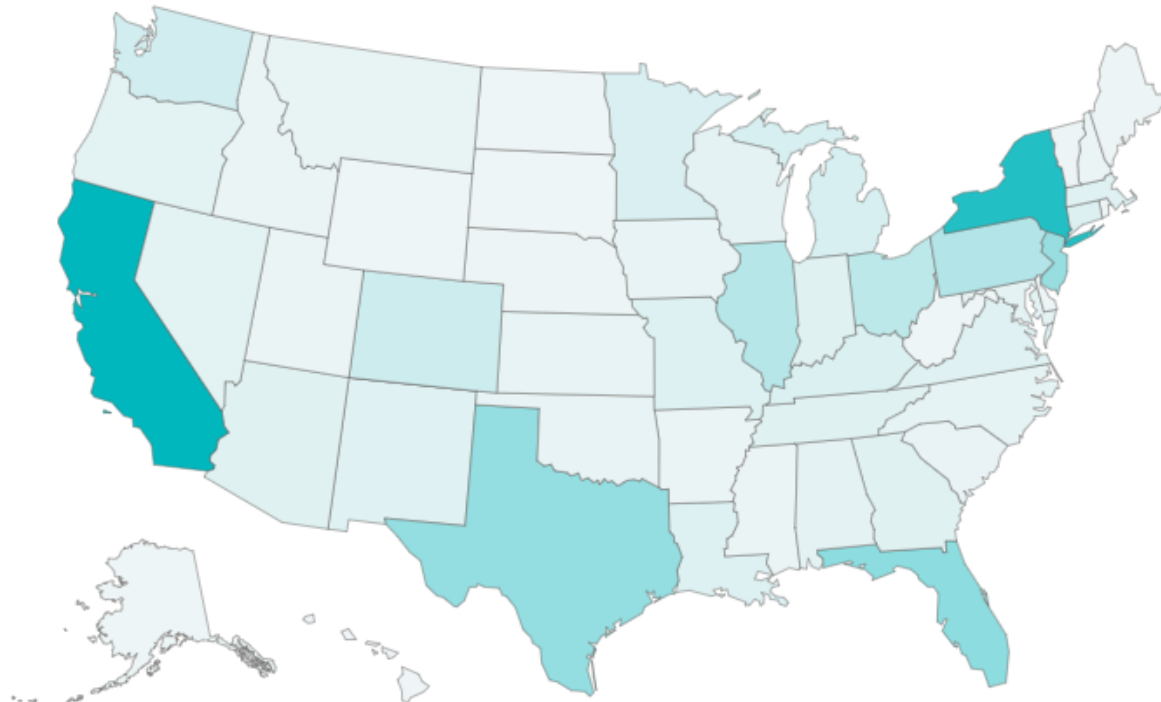
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## COVID-19 Complaint Tracker



Complaints  
**12K**

Last Updated August 10, 2021

### Filing Date

1/30/2020

8/9/2021



### States

State	Complaints
California	2,038
New York	1,747
Florida	832
Texas	777
New Jersey	746
Pennsylvania	515
Illinois	487
Ohio	427
Colorado	290

Detailed Data





# DOCUMENTATION

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# THE 'INTENTION' OF THE MEDICAL RECORD



- Concurrent
  - Communication between providers
- Retrospective
  - Record of care provided
- After the 'infection'
  - Evidence in legal forums



# DOCUMENTATION BEST PRACTICES

- Complete and well organized medical records
  - Notations in records of facility status – at that time
- When residents / patients were first diagnosed and treated
  - Who was notified and when
- Staff training and meetings, update to staffing plans
- Policy changes responsive to state / federal guidance
- Infection control policies, procedures and updates
- Emergency response plan
  - When and how it was implemented



# DOCUMENTATION BEST PRACTICES



- Supply chain evidence
- Efforts to obtain and provide PPE – Masks, gowns, hand sanitizers, etc.
  - Track costs of PPE
  - Invoices
  - Manufacturers numbers
- Efforts to acquire and administer Covid tests
- Practice changes
  - Visitation restrictions
  - Testing protocols and records
  - Social distancing and isolation measures



# DOCUMENTATION BEST PRACTICES



- Memorialize your story
  - What did you know
  - When did you know it
  - What did you do
  - What was happening at the time
  - The experiences of your care-givers
  - Their heroic work
  - Videos
  - Articles
  - Patient / resident / family / community acknowledgements

**THANK YOU  
HEALTHCARE  
HEROES**



# THE SOLUTION

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# MEDICAL CHRONOLOGIES AND TIMELINES

- Medical Chronology
  - Detailed clinical facts documented in chronological format
  - Breakdown of critical information within sub-topics
    - Death
    - Fall
    - Skin breakdown
    - Medication error
    - Abuse
    - **Infection**
- Federal and State Guidance Timelines
- Health Care Organization Response to Guidance



# CASE STUDIES

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# QUESTIONS?

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Thank You

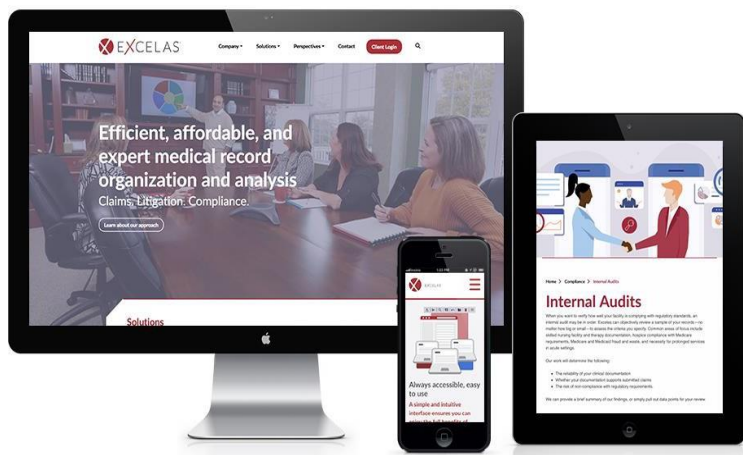


# PROFESSIONAL ORGANIZATION AFFILIATIONS



# PROFESSIONAL LEADERSHIP ORGANIZATIONS





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# THE COVID CHALLENGE

FRIENDS SERVICE ALLIANCE

SEPTEMBER 21, 2020

