




2022 Virtual Regulatory Review Series

Updates on COVID Rules and Responses
Jan. 11, 2022

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Colorado Hospital Association

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- Make sure you are on Zoom and not just called in
- Make sure you are logged into your own computer
- Make sure your name on your Zoom screen includes first and last (no phone numbers)
- Answer polling questions – two questions total
- Complete the evaluation at the end of each session

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GA	NY	WI

For all those who requested CLE credit and answered the polling questions, CLE certificates will be emailed within 48 hours after the session.

For CLE questions, contact Sinead McGuire, Polsinelli department marketing manager, at smcguire@polsinelli.com.

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Today's Presenters & Agenda



Katherine Mulready
SVP and Chief Strategy Officer
Colorado Hospital Association



Joelle M. Wilson
Shareholder
Polsinelli



Colleen Faddick
Shareholder and Practice Chair
Polsinelli

Agenda

- Colorado COVID-19 Update: COVID-19 by the Numbers and Colorado State Government Perspectives
- Telehealth COVID-19 Update: How COVID-19 is Changing Telehealth and Care Delivery
- Responding to COVID-19: Testing, Treatment, and Vaccines; Current Status of Colorado and CMS Vaccine Mandates

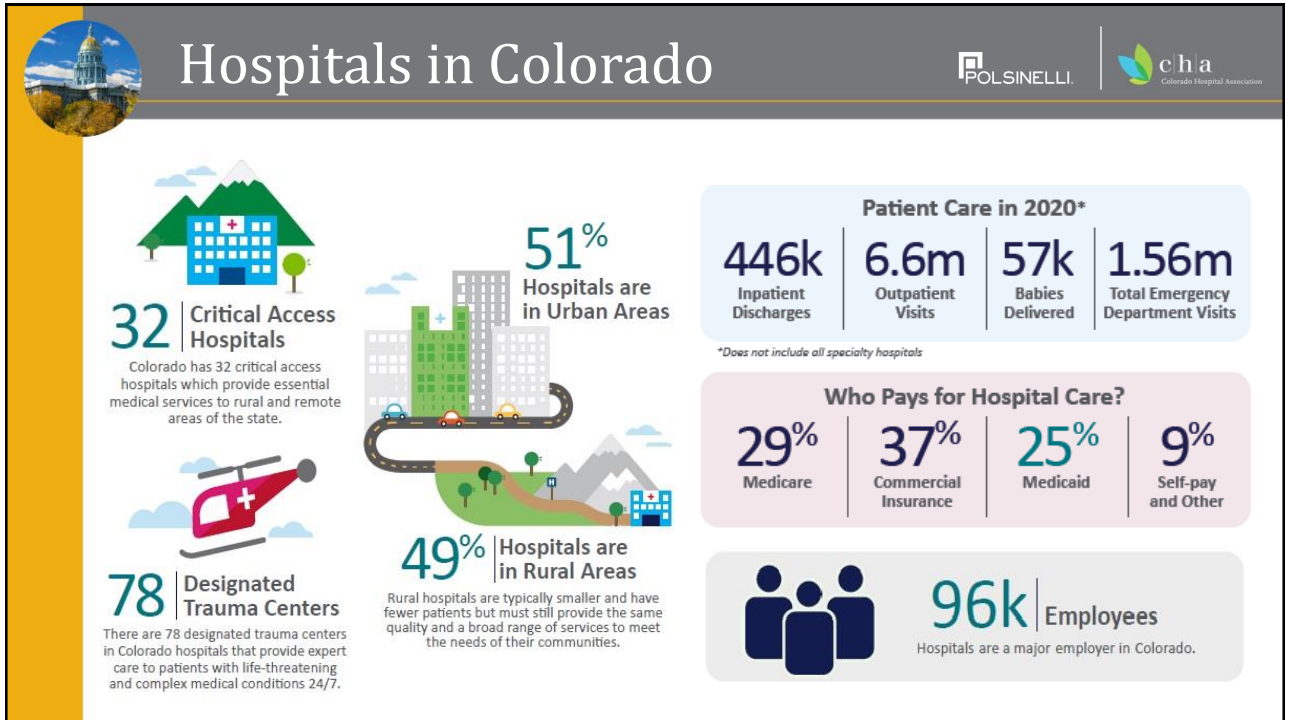
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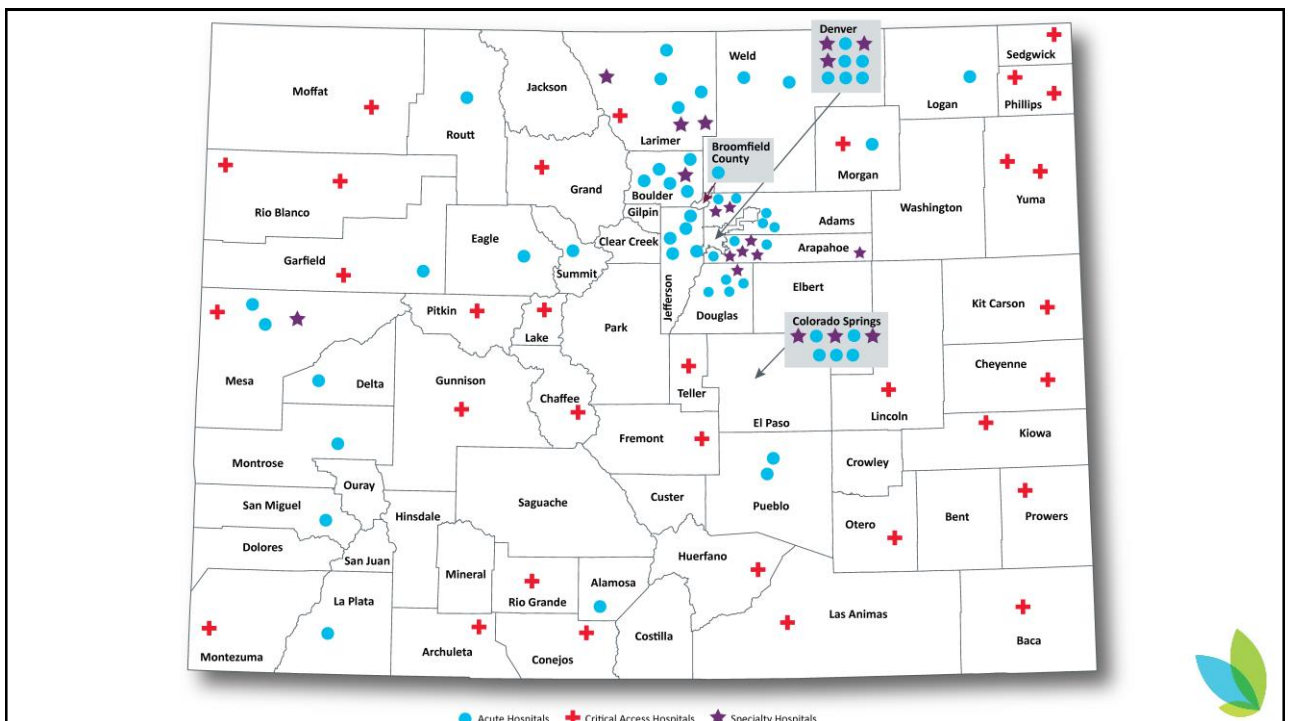
Colorado COVID-19 Update

COVID-19 by the Numbers and Colorado State Government Perspectives

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COVID Priorities

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SPACE



- Increase capacity within the hospital – currently 12,500 licensed beds; 1800+ ICU beds
- Share capacity within and across hot spot areas
- Increase hospital capacity by increasing throughput – support for post-acute settings

SUPPLIES



PPE, Medications, Equipment

- Ramp up PPE manufacturing and acquisition with philanthropic fuel
- Ensure sufficient medications, ventilators for COVID ICU care
- Utilize EMResource to identify needs, line of sight, situational awareness

STAFF



Workforce Extension

- 96,000 existing hospital staff – leverage furloughed and volunteer workforce
- Support for front-line worker childcare and mental health resources

SPENDING



- Loosening restrictions so hospitals can expand surge capacity
- Support for COVID payment mechanisms and federal relief funding
- Apply for grants, and provide information to members for payment and grants

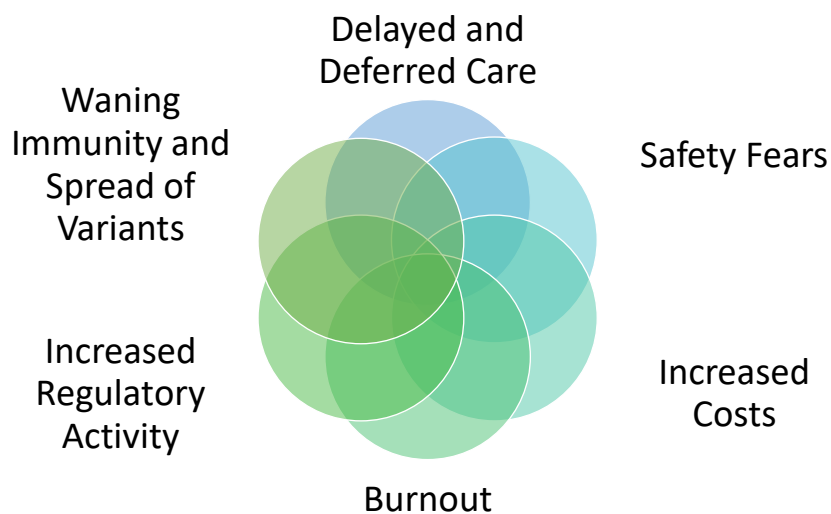
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Current Challenges for Health & Hospitals

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COVID Financial Impacts

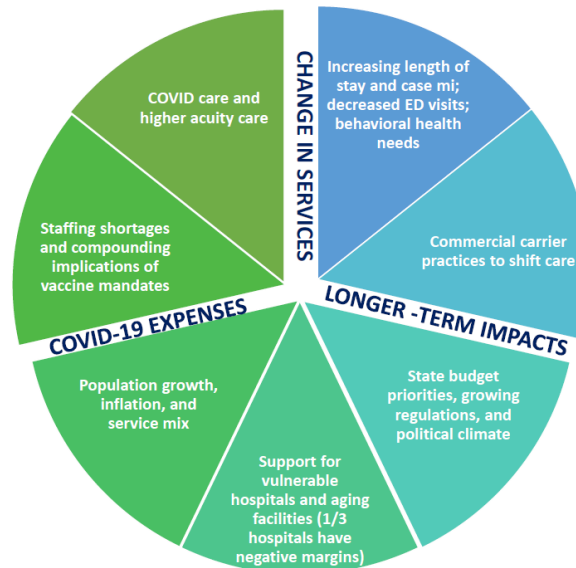


Hospital Expenses

- Shortages in staffing and supplies chain issues are driving-up operational expenses
- Higher acuity patients and continued COVID-19 care

Change in Services

- Decline and shift in hospitals services due to pandemic



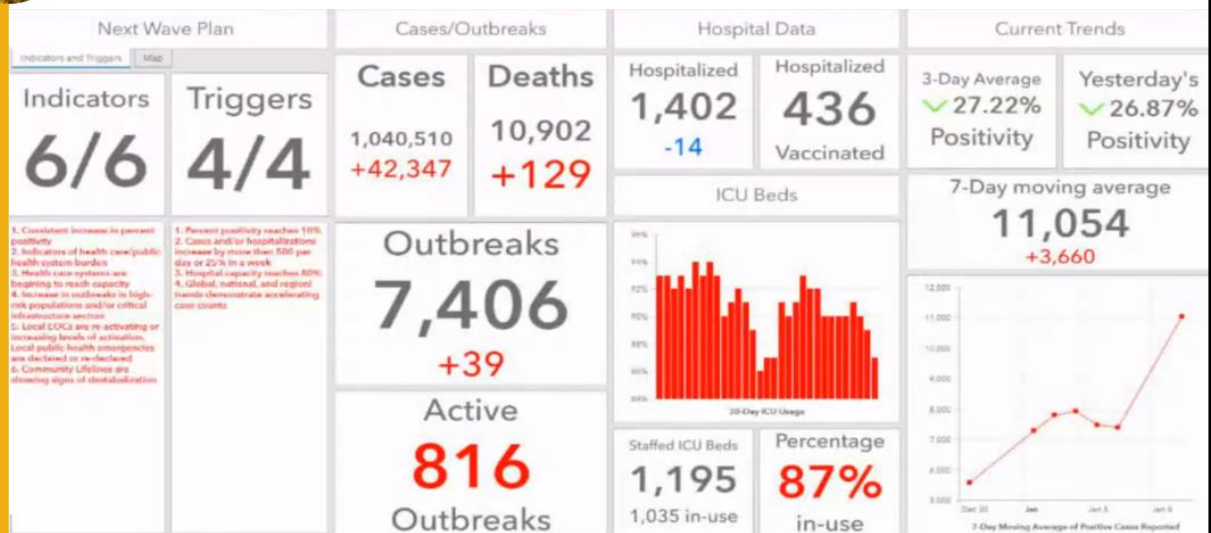
Longer-Term Impacts

- State budget priorities and growing regulation
- Sustaining vulnerable hospitals in communities
- Need for continued investment

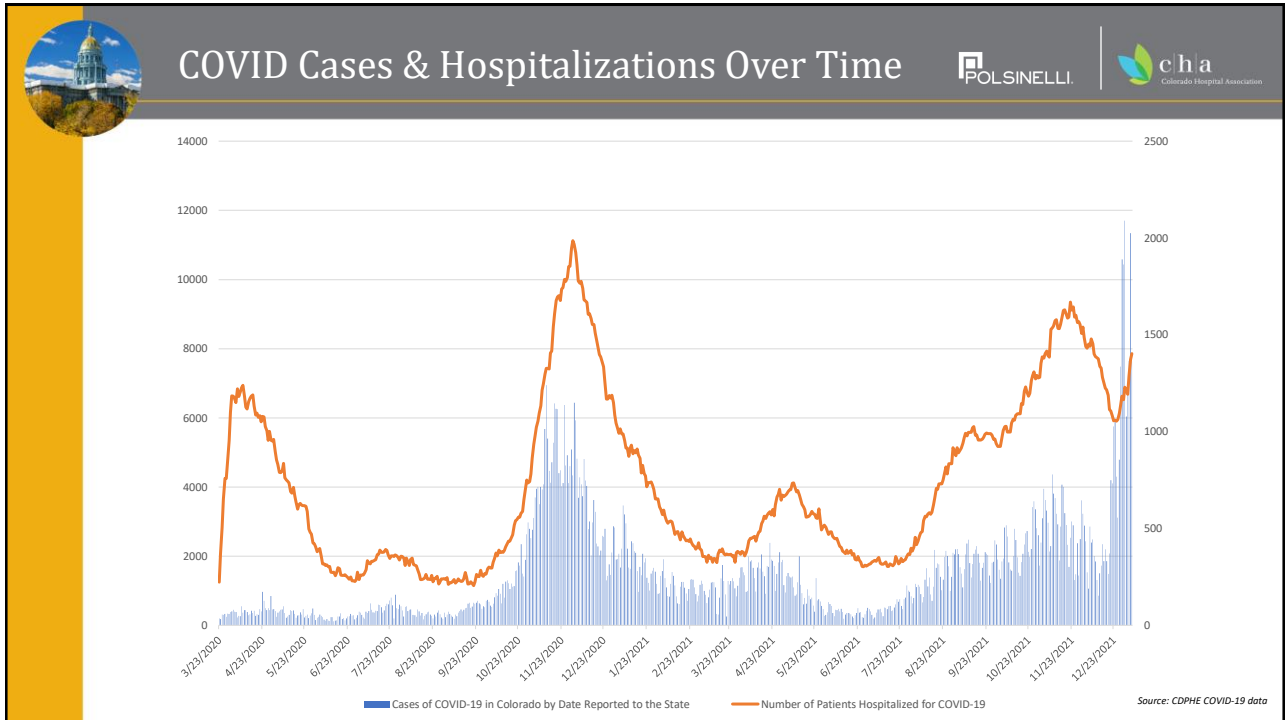
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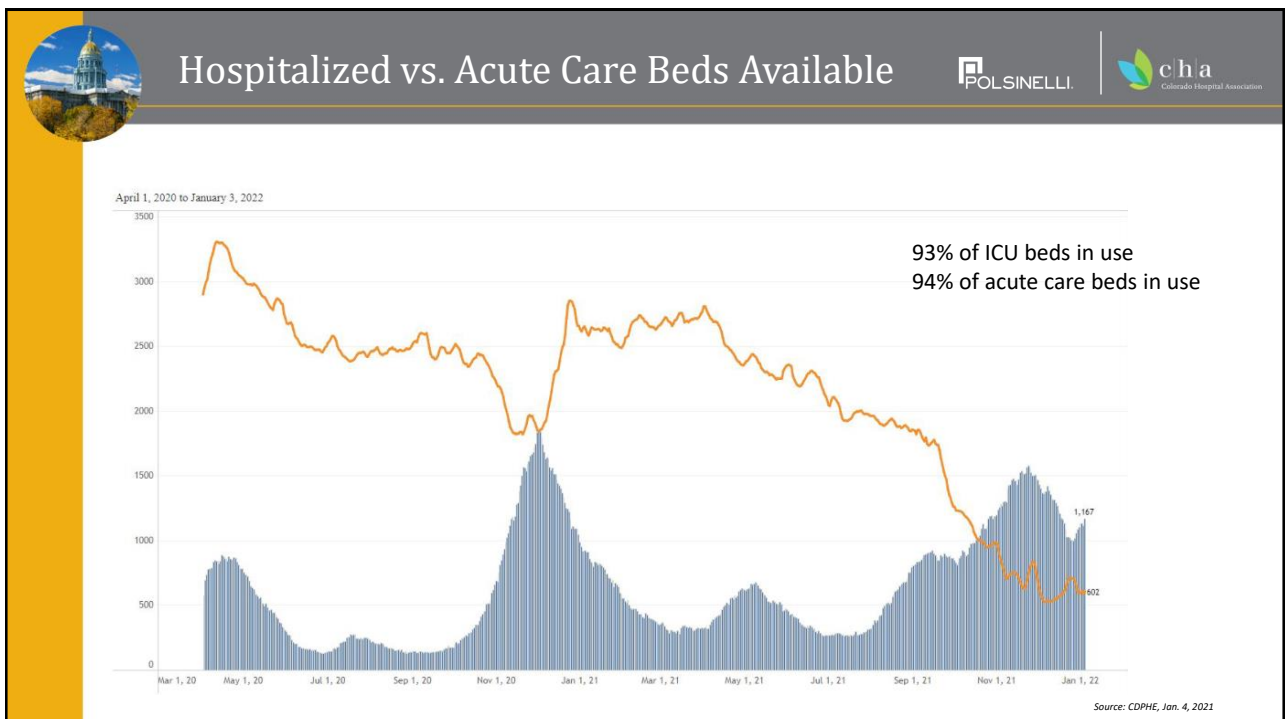
State Daily COVID Dashboard



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Vaccinated vs. Unvaccinated Hospitalizations

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73% of Those Currently Hospitalized are Unvaccinated

354 Vaccinated Hospitalized Patients

954 Unvaccinated Hospitalized Patients

The vaccination status of those currently hospitalized is based on data reported daily to public health by hospitals through the Healthcare Emergency Resource Management system (EMResource). Vaccination status of currently hospitalized individuals is reported in aggregate, and therefore not verified by public health at the patient level. EMResource data provides a snapshot of hospitalizations in Colorado, and is meant to be used for situational awareness. For trends in the vaccination status of hospitalized cases over time, please refer to the COVID-19 Vaccinated & Unvaccinated Case Data dashboard (<https://covid19.colorado.gov/vaccine-breakthrough>).

Source: CDPHE, Jan. 4, 2021

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Trajectories and Hospital Demand

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When will Omicron peak in Colorado and how high will hospital demand reach?

We are narrowing possible trajectories based on current hospital demand

The last two days of data are in-between the 5-week and 6-week wave trajectory

T, Without Omicron, 5-Week Wave: More infectious; 95% reduced hosp. rate, 6-Week Wave: Less infectious; 90% reduced hosp. rate, 8-Week Wave: More infectious; flattened by increase in TC Dec 17 - Jan 28; 85% reduced hosp. rate...

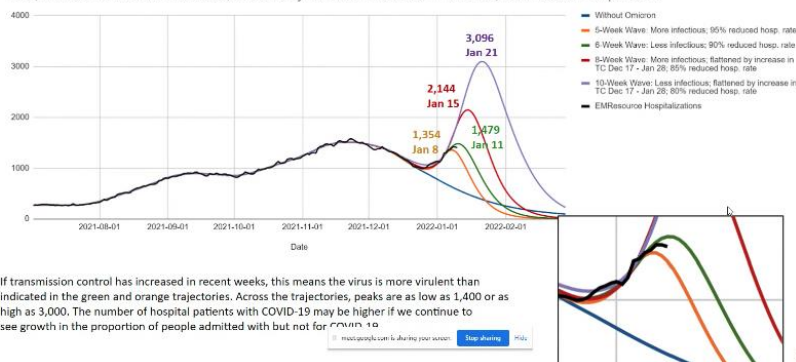


Figure updated
January 10, 2022

Source: Colorado School of Public Health, Jan. 10, 2022

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Top COVID Regulations and Efforts



State Staffing Fusion Center

- Supports facility requests for short-term staff
- Only able to meet demand for 15-20% of facility staffing requests (57 of 273 facilities; 278/2007 personnel requests)

Ensuring Patients Can Access Care

- **Combined Hospital Transfer Center:** statewide coordination across hospitals enables matching of patients and available beds/resources
- **EMS Backup:** state contract with company now able to facilitate patient transfers related to capacity

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Top COVID Regulations and Efforts



Public Health and Executive Orders

- 86 statewide Public Health Orders since May 2020 (five currently active)
- 448 Governor's Executive Orders for COVID (141 in 2021; 307 in 2020)

Crisis Standards of Care

- Currently activated statewide for EMS and health care staffing
- Describe consensus practices for “gracefully degrading” standards from normal to contingency to crisis – as little as possible for as short a time period as possible

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What to Watch: 2022



Other State Policy/Regulatory Efforts: Full Steam Ahead

- State agencies implementing dozens of new laws passed in recent years impacting health care
 - Examples: Colorado Option, Surprise Billing, Hospital Transparency, Rx Affordability Board
- Legislature will move forward with normal operating calendar/procedures
 - Be on the lookout for: Health Workforce, Behavioral Health, Hospital Transparency/Community Benefit, Labor Issues, and many programs in need of financial resources

Election Year

- US Senate, Gubernatorial, Congressional and State House/Senate races: new maps due to 2021 redistricting – shaping policy discussions and driving decisions

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Telehealth: COVID-19 Update

How COVID-19 is Changing Telehealth and Care Delivery

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Telehealth: COVID-19 Updates

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- Telehealth: Blanket term that covers all components and activities that are conducted through telecommunications technology, which includes telemedicine and other technologies like wearable devices and services like remote patient monitoring and virtual health care education.
 - Remote clinical and non-clinical services
- Telemedicine: Use of technologies and telecommunication systems to administer health care to patients who are geographically separated from providers.
 - Remote clinical services

"What is Telehealth?" *NEJM Catalyst Innovations in Care Delivery*, February 1, 2018, <https://bit.ly/3ymYNs7>.

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Telehealth: COVID-19 Updates

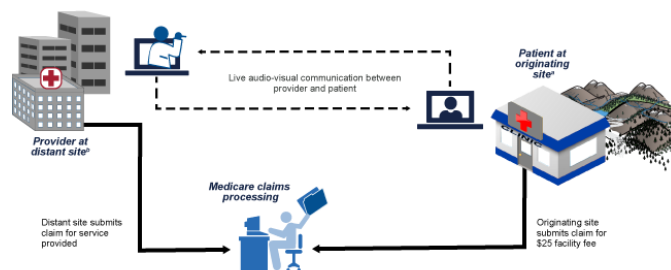
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Medicare Prior to COVID-19

Place of service/originating site (almost exclusively rural health):

- The originating site is the location of beneficiary at time of service
- Telehealth may only be performed at authorized originating sites
- Examples: hospitals, critical access hospitals, rural health clinics, federally qualified health centers



Source: GAO analysis of Medicare statute and regulations. | GAO-17-390T

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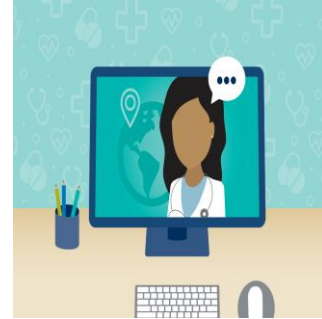


Telehealth: COVID-19 Updates



Medicare Prior to COVID-19

- Telehealth technology:
 - Interactive audio and video telecommunications system.
 - Must be HIPAA compliant
- Established patients only
 - New patients not eligible
 - In-person visit required
- Eligible services
 - Only services listed on Medicare Telehealth Service list may be provided through telehealth
- Eligible providers/distant site practitioners
 - Health care practitioners who are authorized to bill Medicare for their professional services
 - Physicians, nurse practitioners, physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals



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Telehealth: COVID-19 Updates



Medicare During the COVID-19 Public Health Emergency (PHE)

- PHE = Section 1135 Telehealth Waivers and Flexibilities
- Must have both PHE and Presidential Emergency Declaration for CMS to enter waivers under Section 1135 of the Social Security Act (SSA) for Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA)
 - National Coronavirus Pandemic Public Health Emergency (PHE) under Public Health Services Act, 42 U.S.C. §§ 247d-6d, 247d-6e - Secretary HHS Declared PHE Jan. 31, 2020
 - Presidential Emergency Declaration – Declared March 13, 2020

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Telehealth: COVID-19 Updates



Medicare During the COVID-19 Public Health Emergency (PHE)

- **Place of service/originating site requirement**
 - CMS removed geographic limitations and originating site requirements.
 - Medicare beneficiaries may receive telehealth services at any location, including their home.
- **Technology**
 - Most telehealth services must be provided via audio and video .
 - Audio-only services:
 - CMS waiver for audio-only telehealth services (certain counseling behavioral health care and educational services)
 - CY2022 Physician Fee Schedule (PFS) Final Rule – permanent adoption separate payment for HCPCS Code G2252 (virtual check-in)
- **Eligible patients**
 - Telehealth services can be provided to both new and established patients.
- **Eligible services**
 - CMS temporarily expanded the Medicare Telehealth Services list of services that may be furnished via telehealth.
 - ED E/M codes (CPT codes 99281–99285),
 - Critical Care codes (CPT codes 99291 and 99292),
 - Observation codes (CPT codes 99217–99220, 99224–99226, and 99234–99236)
- **Cost sharing**
 - Medicare coinsurance and deductible generally apply to telehealth services, but the HHS Office of Inspector General (OIG) provides flexibility for providers to reduce or waive cost sharing for telehealth services.

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Telehealth: COVID-19 Updates



Medicare During the COVID-19 Public Health Emergency (PHE)

Pre-Pandemic vs. Pandemic Telehealth Use

	Total	Telehealth	E-Visits	Virtual Check-In
Pre-Pandemic (March 2019 - Feb 2020)	910,490	892,121	5,220	14,088
Pandemic (March 2020 – Feb 2021)	28,255,180	27,691,878	367,467	1,601,033

Source: <https://www.cms.gov/medicare-telemedicine-snapshot>

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Telehealth: COVID-19 Updates



Other Federal Considerations

- Drug Enforcement Agency (DEA)
 - Controlled substance prescribing license/registration
 - Registration required in each state in which a practitioner prescribes a controlled substance via telemedicine
 - *Waived for COVID-19 PHE*
- Ryan Haight Act of 2008
 - In-person requirement
 - Exceptions and special registration
 - *In-person requirement waived during the COVID-19 PHE*

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Telehealth: COVID-19 Updates



Medicaid During the COVID-19 PHE

- Medicaid emergency authorities expanded Medicaid capacity, services, and providers during PHE
- Expanded coverage and access to services delivered via telehealth varies by state
- Examples:
 - Distant/originating site requirements
 - Payment parity
 - Increased provider types
 - Increased service types
 - Licensing requirements
 - Technology requirements

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Telehealth: COVID-19 Updates

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State Law Considerations

- Licensure
- Cross-state or multi-state services
- Modality requirements
- Prescribing/controlled substances
- In-person/face-to-face
- New vs. established patient



Colorado

- Limited state flexibilities
- Modality requirements:
 - Audio-only
 - Non-public facing remote communication tools (FaceTime, Skype, etc.)

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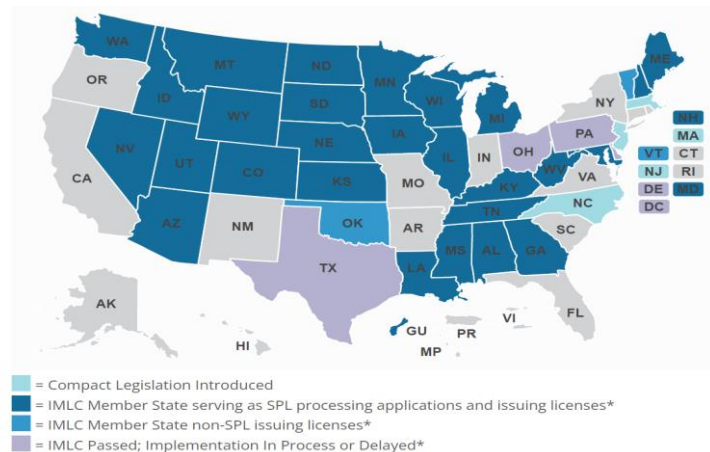
Telehealth: COVID-19 Updates

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Interstate Medical Licensure Compact (IMLC)

- Streamline licensing process for physicians



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Telehealth: COVID-19 Updates



Additional Telehealth Considerations

- Privacy
- Consent
- Credentialing and privileging
- Standard of care
- Scope of practice
- Documentation
- Reimbursement

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Telehealth: COVID-19 Updates



What's Next for Telehealth?

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Polling Question



Medicare beneficiaries can continue to be to receive telehealth services in their home after the Public Health Emergency (PHE) ends?

- True
- False

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Responding to COVID-19

Testing, Treatment, and Vaccines; Current Status of Colorado and CMS Vaccine Mandates

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Current State of Testing



FDA Emergency Use Authorizations

- Molecular – 267 authorizations, inclusive of saliva, pooling and all CLIA complexities (but exclusive of Lab Developed Tests)
- Antigen – 43 authorizations
- Antibody – 87 authorizations
- OTC/Home – 13 antigen, 3 molecular

Reimbursement

- Medicare – must be medically necessary and prescribed by a practitioner (except one test is covered without an order)
- Other payers – CARES Act requires payment for COVID tests furnished by licensed or authorized providers without medical screening by the payer as the individualized assessment for medical necessity is presumed
- OTC tests – generally not covered; recent Biden administration statements suggest coverage will be available “soon”; guidance expected mid-January

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Current State of Testing



Availability

- Demand (surges, variants, travel), availability of tests (reagents and test kits), staffing (adequate licensed lab personnel), cost impact testing availability, and reporting timeliness
- Coordination between manufacturers, state and federal governments is likely needed
- Testing strategies

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Vaccine Mandate - Colorado



Health Care Workers

- Adopted Aug. 30, 2021, revised Dec. 15, 2021
- Applies to all CDPHE-licensed facilities (some cross-over with CMS-certified, but not complete)
- Applies to the facility's employees, direct contractors and support staff:
 - Employees, licensed independent practitioners, students, trainees and volunteers; individuals who provide care, treatment or other services for the facility or its patients, under contract or by other arrangement
 - Excludes: those who exclusively provide telehealth or support services for the facility outside the facility and have no direct contract with clients and other employees, direct contractors or support staff
- Religious and medical exemptions apply; those with exemptions are not required to test, but wear appropriate PPE and socially distance
- Facilities must report their vaccination rate to the Department twice per month (first between 1st – 14th of each month, then between 15th and the last day of the month)

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Polling Question





Colorado hospitals are only subject to a COVID-19 vaccine mandate for their employees once the CMS Mandate is enforced


- True
- False

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Vaccine Mandates - Federal




Centers for Medicare & Medicaid Services





www.osha.gov



www.osha.gov

Omnibus Covid-19 Health Care Staff Vaccination Interim Final Rule (Nov. 5, 2021): most Medicare- and Medicaid-certified providers and suppliers (exclusions, exemptions, no testing opt-out)


Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors (Sept. 9, 2021): federal contractors and subcontractors working pursuant to contract or contract-like instrument (exclusions, exemptions, no testing opt-out)

Occupational Exposure to COVID-19; Emergency Temporary Standard (June 21, 2021): Health care and health care support service workers (no vaccination requirement)



COVID-19 Vaccination and Testing Emergency Temporary Standard (Nov. 5, 2021): large employers with 100+ employees (exclusions, exemptions, testing opt-out, keep documents)

Other Federal Laws
State and Local Government Laws, Orders

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Vaccine Mandate - CMS

Who is Covered?

- Start with the facility type, then consider staff type
- Facilities:

ASC	Home Health Agencies
Hospices	Comprehensive Outpatient Rehabilitation Facilities
Psychiatric Residential Treatment Facilities	Critical Access Hospitals
PACE Providers	Clinics, Rehab Agencies and Public Health Agencies as Providers of Outpatient Therapy Services
Hospitals	Community Mental Health Centers
Long Term Care Facilities	Home Infusions Therapy Suppliers
ICFs-IID	Rural Health Clinics/Federally Qualified Health Centers
ESRD Facilities	
- CMS Requirement does not include non-certified facilities (physician offices, DME, labs, IDTFs, etc.); but consider if physician group has ASC

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Vaccine Mandate - CMS



Who is covered?

- All facility “staff” must be vaccinated (or have an exemption)
- Staff include:
 - Employees, licensed practitioners, volunteers, students and trainees
 - Includes non-clinical personnel such as administrative personnel, housekeeping, food service, volunteer, and other fiduciary board members
 - Anyone who provides care, treatment, or other services for the facility under contract or other arrangement
 - Includes many vendors (clinical and others, such as construction personnel)
 - Location may include those outside of a clinical setting (e.g., a patient’s home)
 - FAQ suggests staff who help or have contact with staff are included

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Vaccine Mandate - CMS



Who is not covered?

- Vaccination requirement does not apply:
 - Even if someone falls within the “staff” definition, the vaccination requirement does not apply to those who exclusively provide telehealth, telemedicine, or support services remotely who do not have any direct contact with patients or other staff
 - Telehealth and remote staff who do interact with other staff (on-site meetings, etc.), likely must comply with the vaccine requirement
 - Vendors who provide infrequent and ad-hoc non-health care services
 - Delivery personnel, repair personnel and others
 - Patients and their visitors

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Vaccine Mandate - CMS



What is required and when?

- Two ways for facilities to comply:
 - Staff must be fully vaccinated by Jan. 4, 2022
 - By Dec. 6, 2021:
 - First dose of Pfizer or Moderna
 - Single dose of J&J
 - By Jan. 4, 2021
 - Second dose of Pfizer or Moderna
 - Staff must have received an exemption from vaccination by Jan. 4, 2022
 - Religious
 - Medical

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Vaccine Mandate - CMS



How is compliance enforced?

- Survey process (e.g., revalidation, complaint) for conditions of participation/conditions for coverage
 - Deficiencies cited with plan of correction opportunity, possible CMPs
 - CMS expects to issue interpretive survey guidelines, along with training for state surveyors (e.g., record review, staff interviews, etc.)

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Vaccine Mandate - CMS



Interplay with state law?

- CMS states the Requirement preempts any inconsistent state law
 - State laws that prohibit employers from requiring vaccination
 - State laws that would limit the types of exemptions available under state law
- The Requirement will unlikely preempt state law with more requirements where employers/facilities can comply with both
 - State laws that require testing of unvaccinated staff
- Colorado Mandate very similar, particularly after the Dec. 15 update:
 - Facilities that are federally certified or undergoing federal certification shall follow all applicable state and federal regulations regarding COVID-19 vaccination. In the event of a discrepancy or conflict between the state and federal regulations, the more stringent standard shall apply.

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Vaccine Mandate - CMS



Court Challenges:

- E.D. Missouri/8th Cir.
 - Eastern District of Missouri enjoined the CMS Mandate in the 10 plaintiff states (Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming)
 - 8th Cir. upheld the injunction
- Dist. of Louisiana/5th Cir.
 - District Court enjoined the CMS Mandate in all 50 states (except that already subject to the E.D. of Missouri injunction)
 - 5th Cir. limited the injunction to only those 14 plaintiff states (Louisiana, Montana, Arizona, Alabama, Georgia, Idaho, Indiana, Mississippi, Oklahoma, South Carolina, Utah, West Virginia, Kentucky, and Ohio)
- Supreme Court
 - Heard arguments on Jan. 7, 2022

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Vaccine Mandate - CMS



Current CMS Stance:

- On Dec. 28, 2021, CMS issued new guidance for the facilities in about 26 states not subject to a federal court injunction
- For compliance, workers in covered health care facilities in these states must (a) obtain the first dose of a COVID-19 vaccine, (b) have a pending request for, (c) have been granted qualifying exemption, or (d) identified as having a temporary delay as recommended by the CDC by Jan. 27, 2022
 - Facilities with >80% vaccination rates and have a plan to meet 100% within 60 days of the date of guidance will not be subject to enforcement actions
 - After 60 days, facilities with >90% vaccination rates and a plan to meet 100% by 90 days of the date of the guidance will not be subject to enforcement actions

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Questions?

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Evaluation



To use the QR code:

- Focus your phone's camera on the code and you will see a link to the survey appear.
- Tap this link and you will be taken directly to the survey.

We encourage everyone to take a moment now to complete the survey.



Next Session:

Out-of-Network Payment and the No Surprises Act

Noon – 1:15 p.m.

Tuesday, Jan. 18

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