

# Regulatory UPDATE



Welcome to the January 2022 edition of the Colorado Hospital Association (CHA) Regulatory Update. Monthly updates cover important information on regulatory issues in the health care field, specifically those associated with the federal government, as well as Colorado state agencies involved in health care issues – including the Colorado Department of Human Services (CDHS), Colorado Department of Public Health and Environment (CDPHE), the Department of Regulatory Agencies (DORA), the Department of Health Care Policy and Financing (HCPF), and the Colorado Department of Labor and Employment (CDLE).

As a reminder, January's CHA Regulatory Briefing Call is scheduled from 10-11 a.m. on Jan. 12. To join, please click on this [link](#). This call allows for informal discussion regarding priority regulatory issues. To receive calendar invites for future calls, please contact Whitney Dolbeer, CHA administrative assistant, at [Whitney.Dolbeer@cha.com](mailto:Whitney.Dolbeer@cha.com) or 720.330.6031.

We hope you'll plan to join CHA and Polsinelli for our annual regulatory review series, which starts Jan. 11. This year's four-part webinar series will look at the many regulatory and policy changes that happened in 2021 or are coming for hospitals and health systems in 2022 in the health regulatory and operational environment in which we live, including state and federal updates. See the full agenda and speaker list [here](#).

- Noon - 1:15 p.m., Tuesday, Jan. 11, 2022 – Session One: Updates on COVID-19 Rules and Responses
- Noon - 1:15 p.m., Tuesday, Jan. 18, 2022 – Session Two: Out of Network Payment and the No Surprises Act
- Noon - 1:15 p.m., Tuesday, Jan. 25, 2022 – Session Three: Stark Law and Fraud & Abuse in Review
- Noon - 1:15 p.m., Tuesday, Feb. 1, 2022 – Session Four: Medicaid Update

[Register here](#) – the registration fee is \$55 for the four-part series. This series is intended for compliance officers, policy, regulatory and legal counsel, government relations, emergency preparedness, public information officers, finance, human relations, behavioral health, quality directors/managers, chief operating officers, chief medical officers, and payer relations.

For questions, contact Peggy McCreary, CHA senior education and events coordinator, at [peggy.mccreary@cha.com](mailto:peggy.mccreary@cha.com).

January's Regulatory Update includes information on the following issues:

- [FDA & NIH Update Treatment Options and Recommendations](#)
- [FDA Identifies Omicron Variant Testing Impacts](#)
- [CDC Updates Pfizer Booster Recommendations](#)
- [CDC Updates Guidance for Health Care Workers Following an Exposure or Positive Test for COVID-19](#)
- [CDPHE Asks Hospitals to Complete a Monoclonal Antibody Survey](#)
- [CDPHE Moves Forward with Vaccine Mandate Updates](#)
- [HHS Distributes Additional Provider Relief Dollars](#)
- [CMS Issues Interpretive Guidance for Vaccine Mandate Rule](#)
- [OSHA Withdraws Non-Recordkeeping Portion of Health Care ETS](#)
- [CHA Provides Guide on Three New Laws Important to Hospitals Effective Jan. 1](#)
- [Colorado Primary Care Payment Reform Collaborative Releases Third Annual Recommendations Report](#)
- [CHASE Board Approves 2022 HPF Model](#)
- [Latest EAPG Base Rates Go into Effect](#)
- [CHA Advocates for Improvements to DOI's Draft Rate Target Methodology](#)
- [Federal Surprise Billing Law Goes into Effect](#)
- [CMS Announces Funding of 1,000 New Residency Slots for Hospitals Serving Rural and Underserved Communities](#)
- [HHS Announces Birthing-friendly Hospital Designation; Issues Guidance on Medicaid and CHIP Option to Extend Postpartum Coverage](#)
- [CHA Secures Medicare Sequester Relief](#)
- [HHS Seeks Public Comments to Advance Equity and Reduce Disparities in Organ Transplantation; Improve Donations and Dialysis Facility Quality of Care](#)
- [Colorado Named Among Four States Selected to Pilot Initiative Advancing Value-based Payments in Health Care](#)
- [Calendar of Key Upcoming Dates](#)

## **COVID-19 Updates:**

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## FDA and NIH Update Treatment Options and Recommendations

On Dec. 22 and Dec. 23, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) of two oral treatments for COVID-19, [Paxlovid](#) and [molnupiravir](#).

The National Institutes of Health (NIH) updated treatment [guidelines and recommendations](#) noting Omicron's markedly reduced susceptibility to the anti-SARS-CoV-2 monoclonal antibodies (mAbs) bamlanivimab plus etesevimab and casirivimab plus imdevimab. However, sotrovimab, another mAb, is expected to retain activity against the variant as is Remdesivir.

## FDA Identifies Omicron Variant Testing Impacts

The FDA has identified potential impacts on performance of COVID-19 tests due to genetic mutations. [Tests expected to fail to detect the SARS-CoV-2 Omicron variant](#) as of Dec. 27:

- Meridian Bioscience, Inc. Revogene SARS-CoV-2 (test is not yet in distribution within or outside of the United States)
- Applied DNA Science Linea COVID-19 Assay Kit

Testing sites across the state continue to see increased demand, longer than usual wait times, and delays in returning test results. CHA will continue to monitor the situation.

## CDPHE Activates Crisis Standards of Care for EMS

On Jan 7, the Chief Medical Officer (CMO) for the Colorado Department of Public Health and Environment (CDPHE) [reactivated the Crisis Standards of Care for Emergency Medical Services \(EMS\)](#). These standards provide guidance for call centers, dispatch centers, and EMS agencies and responders on how to interact with potentially infectious patients, maximize care for multiple patients with limited staff and emergency vehicles, and determine what kind of treatment to provide, such as whether a patient should be transported for further care, if deemed necessary.

## CDC Updates Pfizer Booster Recommendations

The Centers for Disease Control and Prevention (CDC) [updated its recommended](#) interval for booster shots for those who received Pfizer-BioNTech as their primary series from six months to five months. Additionally, CDC is recommending that immunocompromised 5-11-year-olds receive an additional primary dose 28 days after their second shot.

## **CDC Updates Guidance for Health Care Workers Following an Exposure or Positive Test for COVID-19**

On Dec. 24, the CDC updated recommendations on the management of health care personnel with SARS-CoV-2 infection or exposure amid concerns about SARS-CoV-2 Omicron variant and potential impacts on the health care system. Under the CDC's new recommendations, the recommended isolation time for asymptomatic individuals following a positive COVID-19 test is five days; the previous recommended isolation time was 10 days. The five days of isolation should be followed by an additional five days of wearing a mask when around people to minimize the risk of infecting others. Unvaccinated and un-boosted individuals should follow the same recommendations following an exposure to COVID-19. Individuals who have received booster doses do not need to quarantine themselves following an exposure, but should wear a mask for 10 days.

CDPHE confirmed that hospitals can utilize the CDC [guidelines for isolation and quarantine](#) for health care workers. The CDC also updated the [strategies to mitigate health care personnel staffing shortages](#) that augment the conventional strategies. Residential care facilities have the option to adopt the CDC guidelines, they must also continue to follow the [current CDPHE guidance](#), when applicable.

The state provided additional detail on hospitals planning to use the CDC guidelines for isolation and quarantine of health care workers – notably that hospitals must update facility policies to document what level of implementation the hospital is using. “For the regulatory portion of this question, facilities policies should be written to state they follow the national CDC recommendations for a given topic and should then ensure staff are trained on those specific recommendations. In the event of a survey or a complaint investigation, the survey team would hold the facility and staff to being compliant with their own policies and procedures, which reference the CDC standard.”

## **CDPHE Asks Hospitals to Complete a Monoclonal Antibody Survey**

CDPHE's Office of Emergency Preparedness is preparing to receive Evusheld, the COVID-19 monoclonal antibody combination from AstraZeneca, and asking that hospitals complete a brief survey regarding interest in and potential use of the treatment. Evusheld received an FDA EUA late last year for COVID-19 pre-exposure prophylaxis in specific high-risk patients. More details about Evusheld are in this [FDA fact sheet](#).

## **CDPHE Moves Forward with Vaccine Mandate Updates**

On Dec. 15, the Colorado State Board of Health unanimously [voted](#) to extend an emergency rule requiring COVID-19 vaccines for health care workers by 120 days (now set to expire April 2022) and [adopt all changes](#) proposed by CDPHE. The Board of Health passed the [original emergency rule](#) on Aug. 30, 2021, and CHA has prepared a [crosswalk](#) of the changes. Changes to the rule include:

- Removes the testing requirement for unvaccinated staff;
- Replacing the reporting requirement for vaccine compliance from the 1st and 15th of each month to two reporting periods, the 1st – 14th (first period) and the 15th through the last day of the month (second period);
- Expanding vaccination requirements to all eligible staff, both current and new, regardless of clinical responsibility or patient contact;
  - There is a waiver process regarding vaccine mandate waivers for non-patient facing contractors (e.g., construction workers) on a case-by-case basis. Contact Megan Axelrod, CHA manager of regulatory policy, at [megan.axelrod@cha.com](mailto:megan.axelrod@cha.com) with questions.
- Replacing the booster dose requirement with the requirement that facilities develop a plan to encourage personnel to receive a booster dose.

## HHS Distributes Additional Provider Relief Dollars

The Department of Health and Human Services (HHS) [announced](#) distribution of \$9 billion of the \$17 billion in Provider Relief Fund “Phase 4” payments to providers who have experienced revenue losses and expenses related to the COVID-19 pandemic. In addition, HHS stated that it is currently reviewing the remaining Phase 4 applications and will make the remainder of Phase 4 payments in 2022. Approximately 75% of Phase 4 funding is being distributed based on expenses and decreased revenue from July 1, 2020 to March 31, 2021. Smaller providers will be reimbursed at a higher percentage of losses and expenses as compared to larger providers. The remaining 25% of Phase 4 funding is being distributed as “bonus” payments based on the amount and type of services provided to Medicare, Medicaid or Children’s Health Insurance Program patients. HRSA is using Medicare reimbursement rates in calculating these payments.

## CMS Issues Interpretive Guidance for Vaccine Mandate Rule

On Dec. 28, CMS released [interpretive guidance](#), as well as updated its [Frequently Asked Questions](#) for its Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule. In doing so, CMS is pushing back the two original implementation dates for compliance with the vaccine mandate rule. Organizations will now have until Jan. 27 (rather than Dec. 6, 2021) to establish policies mandating vaccines for health care workers and achieve a high level of compliance for the workers to have received their first vaccine. Workers will then have until Feb. 28 (instead of Jan. 4) to complete their primary vaccination series. As a reminder, the Colorado and CMS rules are in alignment concerning relevant staff, boosters, and definition of fully vaccinated.

CHA’s federal consulting firm, Alston & Bird prepared an [analysis of this rule](#).

## OSHA Withdraws Non-Recordkeeping Portion of Health Care ETS

At the end of December, the Occupational Safety and Health Administration (OSHA) [announced on its website](#) that it was “withdrawing the non-recordkeeping portion” of its health care emergency temporary standard (ETS). OSHA emphasized that it would nevertheless “vigorously enforce the general duty clause and its general standards, including the Personal Protective Equipment and Respiratory Protection Standards, to help protect health care employees from the hazard of COVID-19.” OSHA goes on to state that compliance with the standards of the health care ETS will be deemed to meet the general duty clause and, with such a statement, seems to imply that compliance with the infection control portions of the ETS may still be expected.

## State Non-COVID-19 Updates

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### CHA Provides Guide on Three New Laws Important to Hospitals Effective Jan. 1

With the New Year, three new state laws that have gone into effect that will impact Colorado hospitals and health systems: a state law regarding behavioral health licensure, changes to the worker compensation benefit, and the removal of the statute of limitations for sexual misconduct. CHA created [this guide](#) to assist member hospitals and health systems with the implementation. The guide also details the numerous laws that took effect in September 2021. As a reminder, the Association also developed issue briefs on key issues and legislation, as well as an implementation overview, all [available here](#).

The guide also includes a note about the federal surprise billing law that went into effect on Jan. 1 - this will be discussed later in the federal portion.

### Colorado Primary Care Payment Reform Collaborative Releases Third Annual Recommendations Report

In December, the DORA [announced](#) that the Colorado Primary Care Payment Reform Collaborative (PCPRC) has released its [Third Annual Recommendations Report](#). The PCPRC’s annual reports offer findings and recommendations on how to strengthen Colorado’s primary care system through increased investments in advanced primary care delivery and the use of alternative payment models (APMs), which offer financial incentives to promote greater value for patients, purchasers, and providers.

This year's report builds on recommendations from previous years and focuses on four key themes: guiding increased investment in primary care, centering health equity in primary care, integrating behavioral health care within the primary care setting, and increasing collaboration between primary care and public health. The recommendations will guide the Colorado Insurance Commissioner in the development and implementation of affordability standards for health insurance carriers in Colorado.

## **CHASE Board Approves 2022 HPF Model**

On Dec. 14, the Colorado Healthcare Affordability and Sustainability Enterprise (CHASE) Board unanimously approved the 2021-22 Hospital Provider Fee (HPF) model, which will now be sent to the Colorado Medical Services Board (MSB) and to CMS for final approval. The expeditious completion of the model comes after CHA raised concerns about the timing of the model release with HCPF on its Medicaid issues list.

The 2021-22 payments are set at 97% of the upper payment limit (the threshold established by HCPF) resulting in a net gain for Colorado hospitals of \$456 million, a \$46 million (11.2%) increase from the 2020-21 net gain. These amounts represent the highest hospital net gain and largest year-over-year increase since the Medicaid program was expanded in Colorado.

After final approval of the 2021-22 HPF model, HCPF will begin a retroactive reconciliation process to true-up feeds and payments back to October 2020, based on the final 2020-21 HPF model. A separate communication will be sent from CHA to member hospitals and health systems providing detail on each hospital's proposed 2020-21 fee and payment amounts compared to its 2019-20 amounts.

Also on Dec. 14, the CHASE Board unanimously approved changes to the 2023 Hospital Quality Incentive Payment (HQIP) program, as well as the [2022 CHASE Annual Report](#). More information on the CHASE Board and its initiatives is available [here](#).

## **Latest EAPG Base Rates Go into Effect**

On Jan. 1, HCPF's latest Enhanced Ambulatory Patient Groups (EAPG) Hospital Base Rates for all hospitals participating in Health First Colorado went into effect. These rates are specifically for the transition to EAPG version 3.16, impacting outpatient hospital payment, as discussed during HCPF's Hospital Stakeholder Engagement meetings. Hospitals and health systems are encouraged to review their [rate changes](#) and the [hospital engagement meeting materials](#).

Since these rates apply to version 3.16, corresponding payment modeling will need to utilize the [Version 3.16 Weight Table](#). Once federal approval is received, all outpatient hospital claims with first

service dates from Jan. 1, 2022, will be adjusted to reflect the new Hospital EAPG Base Rate and methodology.

## **CHA Advocates for Improvements to DOI's Draft Rate Target**

### **Methodology**

On Dec. 22, CHA [advocated to](#) improve the Division of Insurance's [Colorado Option Rate Target Methodology- DRAFT](#). CHA recommended improving the age band calculation to align with federal law, basing the rate cuts on the average cost plan, and improving their calculation concerning the actuarial benefit of recent additions to the Essential Health Benefits package.

## **Federal Non-COVID-19 Updates**

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### **Federal Surprise Billing Law Goes into Effect**

On Jan. 1, the federal No Surprises Act went into effect to ban surprise billing for federally regulated health plans. In December, CMS released two additional resources to help facilities and providers implement provisions of the No Surprises Act that went into effect. Specifically, the agency released a series of [Frequently Asked Questions](#) related to the good faith estimates that must be provided to uninsured and self-pay patients for most scheduled services or upon request. In addition, the agency, along with the Department of Health and Human Services, released a "[Patient-Provider Dispute Resolution Guidance Package](#)." These guidance documents are intended to help providers, facilities, and uninsured/self-pay patients better understand what information must be included in the good faith estimate and how to initiate the patient-provider dispute resolution process.

### **CMS Announces Funding of 1,000 New Residency Slots for Hospitals Serving Rural and Underserved Communities**

On Dec. 17, CMS issued a final rule that aims to enhance the health care workforce by funding additional medical residency positions in hospitals serving rural and underserved communities. The Fiscal Year (FY) 2022 Inpatient Prospective Payment System (IPPS) final rule with comment period establishes policies to distribute 1,000 new Medicare-funded physician residency slots to qualifying hospitals, phasing in 200 slots per year over five years. Once fully phased in, CMS estimates that the funding of the additional slots will amount to approximately \$1.8 billion over the next 10 years.

In its [press release](#), CMS says it will prioritize the allocation of the new residency slots to hospitals with training programs in areas demonstrating the greatest need for providers, as determined by



[Health Professional Shortage Areas](#). The first 200 residency slots will be announced by January 2023, and will become effective July 1, 2023. For more information, view the [fact sheet](#) or the full FY 2022 IPPS final rule with comment period (CMS-1752-FC3) at the [Federal Register](#).

## **HHS Announces Birthing-friendly Hospital Designation; Issues Guidance on Medicaid and CHIP Option to Extend Postpartum Coverage**

CMS intends to propose adding a “birthing-friendly” hospital designation on its Care Compare website to drive improvements in perinatal health outcomes and maternal health equity, the Department of Health and Human Services (HHS) [announced](#). The designation would initially identify hospitals that provide perinatal care, are participating in a maternity care quality improvement collaborative, and have implemented recommended patient safety practices, HHS said.

Beginning with discharges on Oct. 1, 2021, the Hospital Inpatient Quality Reporting Program asks hospitals to [attest](#) to whether they participate in a statewide and/or national maternal safety quality collaborative and have implemented recommended patient safety practices or bundles to improve maternal outcomes.

CMS also issued [guidance](#) on implementing a temporary state option under the American Rescue Plan Act (ARPA) to provide 12 months of postpartum coverage to pregnant individuals enrolled in Medicaid and the Children’s Health Insurance Program (CHIP) beginning April 1. According to a new HHS [report](#), the number of Medicaid enrollees covered for a full year postpartum would roughly double to 720,000 if every state participated.

## **CHA Secures Medicare Sequester Relief**

On Dec. 10, President Biden signed [S. 610](#) into law, stopping Medicare cuts to hospitals, physicians, and other providers from going into effect early next year. The legislation was passed in both the Senate and House of Representatives earlier in December following advocacy by hospitals and providers across the country, including CHA and member hospital and health systems. The bill extends the moratorium on the 2% Medicare sequester cuts until April 1, reduces cuts from 2% to 1% from April 1 – June 30, and stops the 4% Statutory Pay-As-You-Go (PAYGO) sequester from taking effect early next year.

A full summary of the legislation is linked [here](#).

## **HHS Seeks Public Comments to Advance Equity and Reduce Disparities in Organ Transplantation; Improve Donations and Dialysis Facility Quality of Care**

At the beginning of December, HHS issued a [Request for Information](#) (RFI) through CMS to solicit stakeholder and public feedback that will be used to inform potential changes and future rulemaking to improve the organ transplantation system and seek to enhance the quality of life of those living with organ failure. According to the [press release](#), CMS is focused on identifying potential system-wide improvements that would increase organ donations, improve transplants, enhance the quality of care in dialysis facilities, increase access to dialysis services, and advance equity in organ donation and transplantation. To do this, CMS is calling on collaboration between Organ Procurement Organizations (OPOs), donor hospitals, transplant programs and End-Stage Renal Disease (ESRD) facilities.

CMS' RFI asks the public for specific ideas on advancing equity within the organ transplantation system, particularly on potential changes to the health and safety standards for transplant programs, ESRD facilities, and OPO operations. The feedback will help inform future regulatory requirements that transplant programs, OPOs, and ESRD providers and suppliers would need to meet to participate in the Medicare and Medicaid programs. Comments must be submitted by Tuesday, Feb. 1.

## **Colorado Named Among Four States Selected to Pilot Initiative Advancing Value-based Payments in Health Care**

On Dec. 15, it was [reported](#) that Colorado was named among four states selected to participate in an initiative that aims to improve health care outcomes, equity, and value for Coloradans through implementation of alternative payment models (APMs). According to the article, the announcement was made by Centers for Medicare and Medicaid (CMS) Administrator Chiquita Brooks-LaSure. The new initiative, launched by the U.S. Department of Health and Human Services (HHS) [Health Care Payment Learning Action Network](#) (LAN), creates new [State Transformation Collaboratives](#) (STC) – state-level collaboration efforts between Medicare, Medicaid, and commercial payers to support industry progress in critical areas including advanced primary care, behavioral health integration, and health equity. Arkansas, California, and North Carolina have also been selected to participate.

LAN is a mechanism within HHS that focuses on organizing private, public, and nonprofit health care stakeholders to increase adoption of APMs. Specifically, LAN is intended to coordinate payers, providers, purchasers, patients, product manufacturers, and policy makers to lower cost, improve outcomes, and lower barriers to APM participation.

For more information, view the [press release](#) from HCPF.

## Calendar of Key Upcoming Dates

- **Jan. 11:** 2022 CHA and Polsinelli Virtual Regulatory Review Series
- **Jan. 12:** General Assembly Convenes
- **Jan. 13:** DOI Stakeholder Meeting to Discuss the DRAFT Methodology for Premium Rate Reduction Requirements for the Colorado Option – [Register here](#)
- **Jan. 14:** CHA Board of Trustees Meeting
- **Jan. 14:** DHS Stakeholder Meeting on Creating a Behavioral Health Administration - [Register Here](#)
- **Jan. 14:** HCPF Hospital Stakeholder Engagement Meeting
- **Jan. 14:** SPARC Meeting
- **Jan. 18:** 2022 CHA and Polsinelli Virtual Regulatory Review Series
- **Jan. 18:** HCPF HB21-1198 Implementation Stakeholder Meeting for consumers, advocates, and other stakeholders – [Register Here](#)
- **Jan. 18:** DOI Virtual Permanent Rulemaking Hearing on the Colorado Option Standardized Health Benefit Plan - [Register Here](#)
- **Jan. 18:** DHS Stakeholder Meeting on Creating a Behavioral Health Administration - [Register Here](#)
- **Jan. 19:** CDPHE Board of Health meeting
- **Jan. 19:** HCPF HB21-1198 Implementation Stakeholder Meeting for consumers, advocates, and other stakeholders – [Register Here](#)
- **Jan. 20:** HCPF HB21-1198 Implementation Stakeholder Meeting for providers
- **Jan. 21:** SPARC Meeting – [Register Here](#)
- **Jan. 24:** HCPF Hospital Transformation Program Community Advisory Council
- **Jan. 25:** 2022 CHA and Polsinelli Virtual Regulatory Review Series
- **Jan. 27:** CHA Labor Relations Call
- **Jan. 28:** SPARC Meeting
- **Jan. 28:** CDPHE Suicide Prevention Commission Meeting
- **Feb. 1:** 2022 CHA and Polsinelli Virtual Regulatory Review Series
- **Feb 2:** DOI Prescription Drug Affordability Board Virtual Permanent Rulemaking Hearing on the New Regulation Prescription Drug Affordability Board Definitions and Appeals Process - [Register Here](#)
- **Feb. 16:** CDPHE Board of Health meeting

**\*Member hospitals can access additional information about upcoming rulemaking hearings on the Secretary of State's [website](#).**

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If you are not currently receiving the CHA Monthly Regulatory Update email and would like to be added to the list or for more information, contact Whitney Dolbeer, CHA administrative assistant, at [whitney.dolbeer@cha.com](mailto:whitney.dolbeer@cha.com).



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