

Regulatory UPDATE



Welcome to the February 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, February’s CHA Regulatory Briefing Call is scheduled from 10-11 a.m. on Feb. 9. 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 or 720.330.6031.

February’s Regulatory Briefing will include a presentation on Provider Relief Fund rules from [Brian Lee](#), a regulatory lawyer with CHA’s federal lobbying partner, Alston & Bird, and an expert on federal reimbursement policies and regulations.

February’s Regulatory Update includes information on the following issues:

- [Moderna receives full FDA approval and vaccine for <5 on the horizon?](#)
- [Therapeutics change the landscape of COVID-19](#)
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State COVID-19 Updates

Federal and State Emergency declarations and Public Health Orders Extended and Amended

U.S. Secretary of Health and Human Services (HHS), Xavier Becerra, renewed the national [public health emergency](#) for the COVID-19 Pandemic. The emergency declaration is set to expire on April 16, but may be further extended. HHS has committed a minimum of 60 days' notice prior to expiration, so an update of whether there will be an extension beyond mid-April should be available mid-February.

Governor Jared Polis extended the state's COVID-19 [disaster declaration](#) and Executive Order [D 2022 002](#) on Jan. 27 for another 30 days while the CDPHE extended and amended Public Health Orders (PHO) [20-38](#) and [21-02](#). Amendments to PHO 20-38 remove requirements for individuals at unseated, public indoors events of 500+ people to show proof of vaccination in Arapahoe, Adams, Boulder, and Jefferson Counties as well as the City and County of Denver and the City and County of Broomfield, and 21-02 updated the therapies currently authorized by the Food and Drug Administration (FDA) for the treatment of COVID-19. Many local municipalities along the Front Range allowed indoor masking orders to lapse at the beginning of February. Update pre-sending if applicable

CDPHE updated the [Residential Care Facility \(RCF\) Mitigation Guidance](#) and included a [pre-admission notice](#) to be provided to unvaccinated individuals who are admitting to an RCF during an outbreak. The notice highlights the infection prevention and control measures that the RCF has implemented to protect residents and health care workers from infections and confirms that unvaccinated individuals admitted to an RCF are at increased risk of acquiring COVID-19 and should participate in increased infection prevention measures compared to vaccinated counterparts. Hopefully this will provide some additional relief on the discharge front.

Moderna Receives Full FDA Approval with Vaccine for Five and Under on the Horizon

The FDA gave [full approval](#) to the Moderna COVID-19 vaccine on Jan. 31, which will be marketed as Spikevax. This makes it the second fully approved COVID-19 vaccine available in the United States.

[Pfizer](#) initiated a rolling submission for emergency use authorization for its two-dose vaccine that would be administered to children six months to four years while awaiting data on a three-dose course. Should authorization be granted, Pfizer would be the first COVID-19 vaccine available for pediatric populations under the age of five.

Therapeutics change the landscape of COVID-19

The therapeutics available to combat COVID-19 changed significantly over the last few weeks and CDPHE issued a Health Alert Network Broadcast on Jan. 26 with details on the FDA recommendations.

Clinical information about the optimal management of COVID-19 evolves. Please reference the National Institutes of Health [COVID-19 Treatment Guidelines](#) for the most up to date and complete information regarding COVID-19 therapeutics and their use.

OSHA Vaccine Rule

The [decision](#) by the Supreme Court on January 13 to stay the Occupational Health and Safety Administration's (OSHA) Vaccination and Testing emergency temporary standard (ETS) led the Biden Administration to move to dismiss the petitions challenging the ETS. The withdrawal of the mandate does not preclude individual businesses from implementing vaccine mandates, including state and local governments.

The Centers for Medicare and Medicaid Services (CMS) interim final rule has gone into effect after the [Supreme Court](#) stayed the injunctions against the rule. The ruling of the court should not have an impact here as the Colorado Board of Health issued its own emergency rule in August, 6 CCR 1101-1, Chapter 2 Part 12, mandating that all employees, direct contractors, and support staff in licensed health care settings in Colorado [get vaccinated],” and [amended](#) the rule on Dec. 15 to align with the CMS requirements.

State Transition RFP

CDPHE posted a [Request for Proposals](#) (RFP) to help the state prepare to transition out of its COVID-19 response. The transition will be focused on two fronts, the Public Health Transition Plan and the Health Care Transition Plan. The purpose of this RFP is to find a partner to facilitate feedback from key stakeholders across the state and use this information to develop these two transition plans. The selected partners will be required to complete all specified work by March 31.

Colorado Combined Hospital Transfer Center to De-escalate to Tier 2

The surge from the omicron variant appears to be declining and hospital capacity is experiencing some much needed relief and has been holding steady over the last several days. This has prompted the Combined Hospital Transfer Center (CHTC) to de-escalate to Tier 2. At Tier 2 all hospitals should remain prepared to receive bi-directional transfers from partnered systems, ensure EMResource is updated twice daily and remain in constant contact with partnered system transfer centers. The state has also closed the inter-facility transfer contract with Ambulnz as transfer requests were minimal over the last two weeks.

CHTC will continue to meet weekly and continue to evaluate the triggers for moving up or down a tier.

Crisis Standards of Care Update

The state continues to operate under the staffing and EMS crisis standards of care while urgency to fully activate the standards has subsided. Communication between the state, providers, and systems remain key as the state signals a desire to accelerate its deactivation status.

White House Urged to Investigate Price Gouging by Nurse Staffing Agencies

Following CHA's advocacy, U.S. Representatives Joe Neguse (D-CD2) and Jason Crow (D-CD6) joined nearly 200 House members, to urge the White House COVID-19 Response Team Coordinator Jeffrey Zients to investigate reports that nurse staffing agencies are taking advantage of the COVID-19 pandemic to increase their profits at the expense of patients and the hospitals that treat them.

“We urge you to enlist one or more of the federal agencies with competition and consumer protection authority to investigate this conduct to determine if it is the product of anticompetitive activity and/or violates consumer protection laws,” the representatives said in the [letter](#). “The situation is urgent and the reliance on temporary workers has caused normal staffing costs to balloon in all areas of the country. We have received reports that the nurse staffing agencies are vastly inflating price, by two, three or more times pre-pandemic rates, and then taking 40% or more of the amount being charged to the hospitals for themselves in profits.”

HHS Updates Provider Relief Fund FAQs

In January, HHS updated its [FAQs](#) for the Provider Relief Fund. A redline prepared by CHA’s federal consultants, Alston & Bird, is [linked here](#). Most of the changes cover information regarding Reporting Period (RP) 2 and how changes in RP2 may impact what was submitted in RP1. Notably, HRSA confirmed that choosing a different lost revenue methodology from one RP to another could result in having unused funds to return because the lost revenue has changed. HRSA notes that any changes in the baseline used for comparison and changes to the inputs for each quarter will be calculated and tracked for fluctuations that result from a methodology change. If as a result of the changed lost revenue methodology a Reporting Entity was reimbursed for more lost revenue than they had for the Period of Availability, they may be required to return more funds than they received during the applicable Payment Received Period.

State Non-COVID-19 Updates

OpiSafe - Integrating Colorado’s PDMP into Hospital EHRs

[OpiSafe](#), an opioid risk monitoring tool that incorporates Colorado’s Prescription Drug Monitoring Program (PDMP) into hospitals’ electronic health records (EHRs), is designed to support clinicians prescribing opioids by checking the PDMP prior to opioid orders and prescriptions. By integrating into workflows, OpiSafe also performs risk stratification for each patient based on a variety of criteria to deliver insights at the point of care to prevent, detect, and treat substance misuse. As part of a statewide effort to provide members with access to this tool, and with funding from the Colorado Office of Behavioral Health, CHA has partnered with OpiSafe to support the implementation process and cost for members.

Hospitals and health systems utilizing this tool to support opioid stewardship and other related initiatives will benefit from a variety of features OpiSafe provides, including:

- Delegation of PDMP access
- Toxicology integration
- Medication-assisted treatment (MAT) provider locator
- Time-saving patient risk profiling

Opportunities to discuss the benefits of this tool, as well as the potential for multi-year subsidies, are available.

HCPF Hospital Reports Released

On Jan. 18, HCPF released three reports mandated by state law – the [Annual CHASE Report](#), the [House Bill \(HB\) 19-1001 Hospital Financial Transparency Report](#) and the [HB 19-1320 Community Benefit](#).

Key findings, according to HCPF, in the Hospital Expenditure Report include:

- Net patient revenue for the reporting 57 hospitals grew from \$11.9 billion to roughly \$16.4 billion, an increase of 35.5 percent from 2014, or an average of 5.2 percent each year over the period.
- The figures do not include \$1.07 billion in federal COVID-19 stimulus payments distributed in 2020, which hospitals recorded either as other operating revenue or non-operating revenue.
- Given that the net patient revenue does not include federal COVID-19 stimulus, “it is notable that hospitals’ patient revenues increased between 2019 and 2020 despite the movement of covered lives from commercial to Medicaid due to the COVID-19 pandemic-induced economic downturn, the stay-at-home effort and the hold on elective procedures during the first months of the pandemic.”

According to the Community Benefit report, HCPF asks the General Assembly to consider several additional requirements for hospitals, including obligations and financial penalties for non-compliance with HB 19-1320, requiring additional reporting requirements about how community benefit investments are spent, determining what services and activities constitute community benefits, and more.

CHA released its own [Hospitals: Here for You](#) report, which offers examples of the many ways that Colorado hospitals and health systems are working to improve health care access, affordability, community benefit, and more, and how those efforts are already producing results. CHA will continue to work with legislators and other key stakeholders to explain the value provided to Colorado communities through patient care and community benefit investments, especially during the past two years of the COVID-19 pandemic response.

DOI Releases Insulin Affordability Program Application

The Colorado Division of Insurance (DOI) has developed a [form](#) for individuals to complete to apply for the Insulin Affordability Program, which was created through the passage of [HB 21-1307 – Prescription Insulin Pricing and Access](#). The law establishes two distinct Insulin Affordability Programs:

- One program, the emergency availability program, allows a Colorado resident who pays more than \$100 per month for their insulin and has less than a seven-day supply to secure an emergency, 30-day supply for \$35.
- The second program is for residents who pay more than \$100 for their 30-day supply of insulin to receive a 12-month supply for \$50 per 30-day supply. Plans regulated by the DOI are required to cap the total amount that a covered person is required to pay for insulin at \$100 per 30-day supply.

Pharmacists must provide the [form](#) to their customers in need of such programs and are required to keep the form in their records for two years from the date the insulin is dispensed.

CHA Asks CMS to Address Actuarial Concerns in DOI's 1332 Waiver Request

On Feb. 2, CHA asked CMS to take an oversight role to ensure operational success of the Colorado Option program throughout its review of DOI's [Final- Colorado Section 1332 Innovation Waiver Amendment- 11/30/21](#). Specifically, CHA requested that CMS obtain additional independent actuarial analysis to obtain understanding of the impact of COVID-19 on key variables and gain better insight into the significant differences of estimates for recent benefit changes and account for the fact that differing actuarial assumptions may exist and choose model outputs that reflect more conservative or midpoint estimates.

Surprise Billing Alignment Status

DOI has [scheduled a stakeholder meeting](#) from 1:30pm-2:30 p.m. on Feb. 7 to discuss alignment of the state and federal surprise billing laws. CHA plans to participate in this meeting and will provide an update during the Feb. 9 regulatory call. In advance of that call, CHA flagged initial key questions

and priority areas of alignment for DOI. These areas include: DOI jurisdiction of federally regulated plans, batching arbitration claims, and eliminating duplicative conflicting disclosure requirements.

JBC Preliminarily Approves Two-Percent Provider Rate Increase

On Jan. 28, the Joint Budget Committee took up the first figure setting of the session for Community Provider Rate Common Policies, which applies to most Medicaid providers, including hospitals. JBC staff [presented the Committee with a recommendation](#) for an across the board 2.5 percent provider rate increase, as compared with a 1 percent increase as proposed in the Governor's budget request. Ultimately, the committee compromised and voted unanimously to adopt a 2 percent increase with the potential for some additional targeted increases. While this is great news, it is still early in the process. The Committee has a long way to go in setting the budget and will have to arrive at a balanced budget proposal by late March.

Federal Updates

HHS Announces Availability of \$13 Million to Increase Behavioral Health Care Access in Rural Communities

HHS, through the Health Resources and Services Administration (HRSA), [announced](#) the availability of \$13 million in funding to increase access to behavioral health care services and address health inequities in rural America, including through evidence-based, trauma-informed treatment for substance use disorder.

HRSA's Federal Office of Rural Health Policy will make awards through the Rural Communities Opioid Response Program (RCORP) – Behavioral Health Care Support. Eligible applicants include entities such as Rural Health Clinics, federally recognized tribes, tribal organizations, and community and faith-based organizations.

Applicants can begin the RCORP-Behavioral Health Care Support application process on www.Grants.gov and must apply by midnight (ET) on Wednesday, April 13. Visit the [Notice of Funding Opportunity](#) for more information.

CMS Releases Federal Independent Resolution (IDR) Process Guidance for Disputing Parties

On Feb. 2, CMS joined the HHS, the Department of Labor, and the Department of Treasury to release [guidance](#) regarding the Federal IDR process for disputing parties. This guidance provides direction to disputing parties (also referred to as “the parties”) who are seeking to resolve a claim for payment of out-of-network health care items or services through the Federal IDR process. A health care provider or facility and plan, issuer, or carrier are the “disputing parties” to the Federal IDR process. This guidance provides information to those parties about how they may engage in open negotiation prior to the Federal IDR process, how to initiate the Federal IDR process, how to select a certified IDR entity, and ways to meet the requirements of the Federal IDR process. Additional guidance may be developed in the future to address specific questions or scenarios submitted by the public.

Calendar of Key Upcoming Dates

- Feb. 7: DOI OON Alignment Meeting- [register here](#)
- Feb. 11: HCPF Medical Services Board
- Feb. 16: CDPHE Board of Health Meeting
- Feb. 16: HCPF 1198 Stakeholder Meeting- [register here](#)
- Feb. 18: SPARC Meeting
- Feb. 22: CICIP Stakeholder Advisory Council Meeting (Implementation of HB 21-1198) – [Zoom Webinar](#)
- Feb. 25: SPARC Meeting
- Feb. 25: JBC Figure Setting for DOLA and DORA
- March 1: HCPF 1198 draft rules presentation- [register here](#)
- March 1: JBC Figure Setting for the Office of the Gov and Revenue
- March 3: JBC Figure Setting for HCPF (ED’s Office, Medical Service Premiums, and Office of Community Living)
- March 4: SPARC Meeting
- March 4: HCPF Hospital Stakeholder Engagement Meeting
- March 7: CICIP Stakeholder Advisory Council Meeting
- March 10: JBC Figure Setting for HCPF (Behavioral Health, BH Community Programs, Indigent Care, and Other Medical Services)
- March 11: SPARC Meeting
- March 15: JBC Staff Comeback Figure Setting
- March 17: March Revenue Forecast

- March 18: SPARC Meeting

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

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.



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