

MMHPI COVID-19 Regulatory & Reimbursement Newsletter

Letter to Providers #40: State and Federal Updates – January 15, 2021

Contents

Texas Updates	2
State Emergency Declaration Extended	2
Reimbursement Rate Updates for Procedure Codes 86408 and 86409	2
Several Regions Added to “High Hospitalization” List.....	2
Alternate Care Site in Austin To Expand Hospital Capacity Established	3
Vaccine Hub Providers for Week of January 11	3
Texas Issues Phase 1 Vaccine Best Practices	4
DSHS Issues Dual Reporting Reminder.....	4
NF and ALF Providers: New COVID-19 Vaccination Data Reporting Emergency Rules	5
Therapeutics Updates.....	5
Federal Updates.....	6
HHS Renews Public Health Emergency.....	6
HHS Launches Web-Based Locator for COVID-19 Outpatient Treatment Sites	6
HHS Continues Community-Based Testing Sites for COVID-19	6
Testing, Vaccination Funding for State, Local Governments.....	7
FDA Statement on Moderna Dosing Schedule	7
Moderna COVID-19 Vaccine Frequently Asked Questions.....	7
Genetic Variants of SARS-CoV-2 May Lead to False Negative Results	8
CDC Updates and Reports	8
Allergic Reactions to COVID-19 Vaccines.....	8
Updated Strategies to Optimize PPE	9
Opening of Large Institutions of Higher Education and County-Level COVID-19 Incidence	9
Mitigation Policies and COVID-19–Associated Mortality in 37 European Countries.....	10
CMS Launches Automated Web Tool for Public Health Emergency-Related Inquiries.....	10

With federal and state health care policies changing in response to COVID-19, the Meadows Mental Health Policy Institute (MMHPI) is issuing *COVID-19 Regulatory & Reimbursement Newsletters* to support providers. In these newsletters, we highlight recent changes and extensions to regulatory and reimbursement rules, as well as newly published or updated guidance and answers to frequently asked questions.

These newsletters, along with additional information on mental health resources during a pandemic, are posted here: <https://mehpi.org/work/covid19/>. If you would like to have additional organizations added to our distribution list or have follow up questions on the content, please email Catie Hilbelink at chilbelink@mehpi.org.

Texas Updates

State Emergency Declaration Extended

Date	January 5, 2021
Summary	Gov. Abbott extended the state disaster declaration for an additional 30 days. The declaration now expires February 4, 2021.
Link	https://gov.texas.gov/news/post/governor-abbott-renews-covid-19-disaster-declaration-in-january-2021

Reimbursement Rate Updates for Procedure Codes 86408 and 86409

Date	January 12, 2021
Summary	Effective December 29, 2020, for dates of service on or after August 10, 2020, the reimbursement rates for COVID-19 related laboratory testing procedure codes 86408 and 86409 have been updated. The following link shows the updates: COVID-19 procedure codes 86408 and 86409
Link	https://www.tmhp.com/news/2021-01-12-reimbursement-rate-updates-procedure-codes-86408-and-86409-effective-august-10-2020

Several Regions Added to “High Hospitalization” List

Date	January 10, 2021
Summary	A number of trauma service areas (TSAs) have reached the state’s seven-day threshold for “high COVID-19 hospitalizations” and have been or soon will be asked to scale down elective surgeries and procedures. As a reminder, executive orders GA 31 and 32 lay out the threshold for high hospitalizations and impact on elective

procedures. Areas of northeast Texas (TSA F), central Texas (TSAs L and O), southeast Texas (TSA Q), and the Lower Rio Grande Valley (TSA V) have met the high hospitalization threshold recently.

Link	https://www.dshs.state.tx.us/GA3031/
-------------	---

Alternate Care Site in Austin To Expand Hospital Capacity Established

Date	January 12, 2021
Summary	Gov. Abbott announced that the Texas Division of Emergency Management (TDEM), in partnership with Travis County, the city of Austin, and the Capital Area Trauma Regional Advisory Council, has established an Alternate Care Site in Austin to expand hospital capacity in the region. Opening on January 12 at the Austin Convention Center, the facility will provide central Texas with additional hospital beds, medical equipment, and medical personnel to assist with the region's COVID-19 response. The facility has a capacity of 25 beds and can expand to more beds if needed.
Link	https://gov.texas.gov/news/post/state-of-texas-establishes-alternate-care-site-in-austin-to-expand-hospital-capacity

Vaccine Hub Providers for Week of January 11

Date	January 10, 2021
Summary	The Texas Department of State Health Services (DHS) instructed the Centers for Disease Control and Prevention (CDC) to ship first doses of COVID-19 vaccine to 234 Texas providers this week. This includes 28 hub providers that will focus on large community vaccination efforts as Texas vaccinates health care workers, people 65 and older, and those with medical conditions that put them at greater risk of hospitalization and death from COVID-19. The <u>hub providers</u> will receive 158,825 doses of vaccine based on the number of people each provider estimated it could serve in a week. An additional 38,300 doses will go to other providers to continue vaccination in communities statewide. Providers in 104 counties will receive vaccine shipments this week, bringing the cumulative number of counties to 222. The vaccine has been administered to residents of all 254 Texas counties.
Link	https://dshs.texas.gov/news/releases/2021/20210110.aspx

Texas Issues Phase 1 Vaccine Best Practices

Date	January 11, 2021
Summary	<p>On a state webinar with providers that will be receiving vaccine for large-scale vaccination efforts, Texas officials showcased a "best practices" document that articulates rules related to residency requirements, copays, second doses, and other issues. The state emphasized that the expectation is to exhaust all doses every week and create a waitlist by eligibility with contact information for those on the waitlist.</p> <p>Other key elements noted on the call:</p> <ul style="list-style-type: none"> • Reporting has never been more critical. Providers must fulfill the dual-reporting requirement. • The state intends to continue providing large amounts of vaccine to these sites if they are able to handle the logistics and reporting. • Vaccinators cannot charge a copay to the patient, and there is no residency requirement to receive the vaccine. • Vaccine registration links must be made public. • Providers must ensure they have internal protocols to ensure second-dose vaccinations match the first dose for every individual.
Link	https://www.dshs.state.tx.us/immunize/covid19/VaccineProviderBestPractices.pdf

DSHS Issues Dual Reporting Reminder

Date	January 7, 2021
Summary	<p>DSHS reminded providers of the dual-reporting requirement for COVID-19 vaccinations. In addition to current daily reporting to ImmTrac2, all providers are required to report data on doses administered through the TDEM portal by 8 a.m. CT every day. DSHS indicated that dual reporting is an interim requirement until data can consistently flow in ImmTrac2. Hospitals that already report therapeutic data through the TDEM portal don't need to be provisioned into the system. TDEM will email the remaining facilities to set up a reporting account. Note that if doses are not reported by 8 a.m., TDEM will reach out by phone to collect the outstanding data for that day. The calls are to ensure timely, accurate data on doses administered, which will be posted online daily. The ImmTrac2 data will still be used to generate comprehensive data on age, gender, and county. DSHS is working quickly to resolve the ImmTrac2 data submission issues. In the meantime, this additional reporting requirement is mandatory. See TDEM's instructions for accessing and reporting information in the portal. Contact vaccine@tdem.texas.gov with questions about the portal.</p>

Link	https://www.tha.org/Portals/0/files/COVID-19/Reporting_COVID-19_Vaccines_and_Therapeutics.pdf?ver=2021-01-07-174926-423
-------------	---

NF and ALF Providers: New COVID-19 Vaccination Data Reporting Emergency Rules

Date	January 11, 2021
Summary	<p>Effective January 11, 2021, the Texas Health and Human Services Commission (HHSC) adopted new COVID-19 vaccination data reporting emergency rules. The rules require nursing facilities (NFs) and assisted living facilities (ALFs) to accurately report COVID-19 vaccination data for staff and residents to HHSC in the format established by HHSC within 24 hours of completing a round of vaccinations. The data will allow HHSC to accurately track vaccinations of staff and residents in long-term care facilities in Texas. HHSC published Provider Letter 2021-01 with instructions on how to report vaccination data information to HHSC using Survey Monkey. Facilities must begin reporting vaccination data immediately using an online survey.</p> <p>Read the nursing facility emergency rules. Read the assisted living facility emergency rules.</p>

Therapeutics Updates

Date	January 9, 2021
Summary	<p>Gov. Abbott announced that TDEM has established two new COVID-19 therapeutic infusion centers in Fort Worth and Irving. The infusion centers will begin accepting patients on Monday and have been provided with Regeneron's monoclonal antibodies and bamlanivimab to treat outpatient cases of COVID-19 who meet certain criteria and have a referral from a hospital or doctor.</p> <p>These two new infusion centers are the latest to be launched by the State of Texas. Previous centers have been established in El Paso, Laredo, Harlingen, and Austin to help communities combat COVID-19 and reduce hospitalizations.</p>
Link	https://gov.texas.gov/news/post/governor-abbott-tdem-establish-covid-19-therapeutic-infusion-centers-in-fort-worth-irving

Federal Updates

HHS Renews Public Health Emergency

Date	January 7, 2021
Summary	The United States Department of Health and Human Services (HHS) formally renewed the COVID-19 public health emergency declaration effective January 21, 2021. The 90-day extension will help hospitals and health systems combat COVID-19 in their communities.
Link	https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-07Jan2021.aspx

HHS Launches Web-Based Locator for COVID-19 Outpatient Treatment Sites for Monoclonal Antibodies

Date	January 11, 2021
Summary	A web-based COVID-19 outpatient treatment locator maintained by HHS is now available to assist healthcare providers and patients in finding potential locations for treatment with monoclonal antibody therapeutics. These medicines are authorized for emergency use in treating patients with mild or moderate COVID-19 who are at high risk of developing severe symptoms and requiring hospitalization.
Link	https://www.hhs.gov/about/news/2021/01/11/hhs-launches-web-based-locator-for-covid-19-outpatient-treatment-sites-for-monoclonal-antibodies.html

HHS Continues Community-Based Testing Sites for COVID-19

Date	January 7, 2021
Summary	HHS announced the extension of the Community-Based Testing Site program for COVID-19 testing, through partnerships with national pharmacy and retail chains CVS, Rite-Aid, Walgreens, Quest (through services at Walmart) and service provider eTrueNorth (through services at Health Mart and Topco locations). The program will continue to operate into April 2021 as a result of a \$550 million funding extension. The partnership has resulted in establishing more than 3,300 COVID-19 testing locations in all 50 states, the District of Columbia, and Puerto Rico. To date, more than 5.6 million tests have been conducted as a result of this partnership.
Link	https://www.hhs.gov/about/news/2021/01/07/hhs-continues-community-based-testing-sites-covid-19.html

Testing, Vaccination Funding for State, Local Governments

Date	January 6, 2021
Summary	HHS announced the CDC will distribute over \$22 billion to support COVID-19 testing and vaccination for state and local governments before January 19, 2021. Texas will receive about \$1.5 billion for testing, contact tracing, surveillance, containment, and mitigation to prevent spread; in addition, the city of Houston will receive \$133.5 million. Texas, excluding Houston and San Antonio, will receive \$227 million for vaccination efforts. Houston will receive \$21 million and San Antonio will receive \$14 million for vaccination. See the testing and vaccine funding tables for more.
Link	https://www.hhs.gov/about/news/2021/01/06/hhs-announces-22-billion-in-funding-to-support-expanded-testing-vaccination-distribution.html

FDA Statement on Moderna Dosing Schedule

Date	January 4, 2021
Summary	Following discussions about cutting doses of Moderna's vaccine in half to double its supply and speed up distribution, the Food and Drug Administration (FDA) reiterated its position in a statement: vaccinators must adhere to authorized dosing schedules. FDA emphasized the importance of receiving doses as they have been authorized by the agency to ensure vaccine efficacy observed in large-scale clinical trials.
Link	https://www.fda.gov/news-events/press-announcements/fda-statement-following-authorized-dosing-schedules-covid-19-vaccines

Moderna COVID-19 Vaccine Frequently Asked Questions

Date	January 5, 2021
Summary	FDA posted a new webpage, Moderna COVID-19 Vaccine Frequently Asked Questions. Questions cover specifics, such as what data did the FDA review when deciding whether to authorize the vaccine for emergency use, how well the vaccine prevents COVID-19, and more.
Link	https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/moderna-covid-19-vaccine-frequently-asked-questions

Genetic Variants of SARS-CoV-2 May Lead to False Negative Results

Date	January 8, 2021
Summary	FDA alerted clinical laboratory staff and health care providers that genetic variants of SARS-CoV-2 may lead to false negative results with molecular tests for SARS-CoV-2. The Letter to Clinical Laboratory Staff and Health Care Providers includes important information about potential false negative results with molecular tests, including: <ul style="list-style-type: none">• Details on the effect of genetic variants on test performance.• Recommendations for clinical laboratory staff and health care providers.• Actions the FDA has taken.• Instructions for reporting problems with a test.
Link	https://www.fda.gov/medical-devices/letters-health-care-providers/genetic-variants-sars-cov-2-may-lead-false-negative-results-molecular-tests-detection-sars-cov-2

CDC Updates and Reports

Allergic Reactions to COVID-19 Vaccines

Date	January 15, 2021
Summary	CDC reported 21 cases of anaphylaxis among 1.9 million people who received the first dose of the Pfizer vaccine between December 12 and 23. The estimated 11.1 cases per 1 million doses is higher than the 1.3 cases per 1 million doses associated with the flu vaccine. More than 70% of the 21 Pfizer cases occurred within 15 minutes of vaccination. 17 people had a documented history of allergies or allergic reactions, and all but two cases were treated with epinephrine. Ultimately, four patients were hospitalized, 17 were treated in an emergency department and all recovered. Only one case was reported among more than 224,000 people who received the first dose of the Moderna vaccine over the same period. An in-depth Moderna report is forthcoming.
Link	https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm

Updated Strategies to Optimize PPE

Date	December 29, 2020
Summary	CDC updated its summary for health care facilities to optimize personal protective equipment (PPE) during shortages. The summary is a quick reference guide and provides links to specific guidance. These strategies offer a continuum of options using the framework of surge capacity when PPE supplies are stressed, running low or absent. When using these strategies, facilities should: <ul style="list-style-type: none"> • Consider these options and implement them sequentially. • Understand their current PPE inventory, supply chain, and utilization rate. • Train health care personnel on PPE use and have them demonstrate competency with putting on and taking off any PPE ensemble that is used to perform job responsibilities. • Once PPE availability returns to normal, promptly resume conventional practices.
Link	https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/strategies-optimize-ppe-shortages.html

Opening of Large Institutions of Higher Education and County-Level COVID-19 Incidence

Date	January 8, 2021
Summary	CDC found U.S. counties with large colleges or universities with remote instruction experienced a 17.9% decrease in incidence, and university counties with in-person instruction experienced a 56% increase in incidence, comparing the 21-day periods before and after classes started. Counties without large colleges or universities experienced a 6% decrease in incidence during similar time frames. Additional implementation of effective mitigation activities at colleges and universities with in-person instruction could minimize on-campus COVID-19 transmission and reduce county-level incidence.
Link	https://www.cdc.gov/mmwr/volumes/70/wr/mm7001a4.htm?s_cid=mm7001a4_w

Mitigation Policies and COVID-19–Associated Mortality in 37 European Countries

Date	January 12, 2021
Summary	CDC found European countries that implemented more stringent mitigation policies earlier in their outbreak response tended to report fewer COVID-19 deaths through the end of June 2020. These countries might have saved several thousand lives relative to countries that implemented similar policies, but later. An increase by one standard deviation in policy stringency at an early timepoint was associated with 12.5 cumulative fewer deaths per 100,000 on June 30. Earlier implementation of stringent mitigation policies, even by just a few weeks, appears to be important to prevent widespread COVID-19 transmission and reduce the number of deaths.
Link	https://www.cdc.gov/mmwr/volumes/70/wr/mm7001a4.htm?s_cid=mm7001a4_w

CMS Launches Automated Web Tool for 1135 Waiver Requests and Public Health Emergency-Related Inquiries

Date	January 11, 2021
Summary	The Centers for Medicare & Medicaid Services (CMS) launched a web-based platform to help standardize “Section 1135” waiver requests and other Public Health Emergency (PHE)-related inquiries the agency receives. Under Section 1135 of the Social Security Act (the Act), the Secretary of Health and Human Services may waive selected provisions of Titles XVIII, XIX, and XXI of the Act in the event of an emergency declared by the President and the Secretary. Available from CMS.gov’s Waivers and Flexibilities webpage, the web tool’s user-friendly submission process will reduce burden on providers by streamlining how they document and submit 1135 waiver requests and PHE-related inquiries. It also will enhance how CMS reviews waivers and inquiries, which can now be submitted any time, any place, and for an array of qualifying emergencies.
Link	https://www.cms.gov/newsroom/news-alert/cms-launches-automated-web-tool-1135-waiver-requests-and-public-health-emergency-related-inquiries