



Health Care Regulation Guidance Letter

Number: GL 20-0002
Title: Regulatory Compliance During the COVID-19 Disaster
Provider Types: Abortion Facilities, Ambulatory Surgical Centers, Birthing Centers, Chemical Dependency Treatment Facilities, Community Mental Health Centers, Comprehensive Out-Patient Rehabilitation Facilities, Crisis Stabilization Units, End Stage Renal Disease Facilities, Freestanding Emergency Medical Care facilities, General and Special Hospitals, Laboratories certified under Clinical Laboratory Improvement Amendments (CLIA), Licensed Chemical Dependency Counselors, Narcotic Treatment Programs, Portable X-Ray Services, Private Psychiatric Hospitals, Rural Health Clinics, and Special Care Facilities
Date Issued: April 28, 2020

1.0 Subject and Purpose

This letter provides guidance to regulated health care facilities and licensed professionals on how the Health and Human Services Commission (HHSC) is establishing and enforcing compliance with regulations during the COVID-19 disaster.

This guidance applies only to HHSC state enforcement actions. While HHSC conducts surveys and makes recommendations to the Centers for Medicare and Medicaid Services (CMS) for federal enforcement action, CMS is ultimately responsible for all federal enforcement decisions.

2.0 Policy Details & Provider Responsibilities

HHSC acknowledges that full compliance with state and federal laws, regulations, and guidance documents may be difficult during the COVID-19 disaster.

HHSC expects facilities and professionals that it regulates to make every effort to achieve full compliance, document all efforts to comply and any

reasons compliance proved difficult or impossible, and maintain a written record of the attempted compliance.

Certain state laws and rules have been suspended by the Governor. In addition, some federal authorities have issued multiple waivers relieving providers of certain requirements. **To the extent that these laws and rules are not in effect at this time, HHSC will not investigate allegations of violations of these laws or rules.** This means that HHSC also will *not* pursue enforcement action related to violation of laws or rules that have been suspended, waived, or otherwise modified by federal or state authorities.

Note: This guidance letter does not necessarily apply to CMS federal enforcement actions because CMS is ultimately responsible for all federal enforcement decisions, as stated above. Please refer to CMS federal guidance for any federal initiatives and decisions regarding inspections/investigations/enforcement.

Note: Facilities that have changed capacity under emergency rules will be required to revert to their original occupancy and certification requirements as required by HHSC, or upon the termination of the Governor's disaster declaration.

HHSC will follow its standard process for investigating any issue and will provide a facility with all due process during an investigation and any subsequent compliance or enforcement, including the opportunity to provide HHSC with relevant information.

As noted above, HHSC recommends that providers make every effort to achieve full compliance with federal and state laws and rules that remain in effect, document all efforts to comply and reasons compliance was difficult or impossible, and maintain a written record of attempted compliance.

If a provider is investigated for an alleged violation of federal or state law or rule, and compliance with the law or rule was affected by the COVID-19 disaster, the provider's response to the COVID-19 disaster, or other relevant factors, HHSC will appropriately consider documented attempts at compliance, documented reasons for non-compliance, and other relevant mitigating factors in its review of violations or non-compliance.

All CMS guidance issued to licensed facilities regulated by the federal government is provided at <https://www.cms.gov/About-CMS/Agency-Information/EPRO/Current-Emergencies/Current-Emergencies-page> (also linked below).

3.0 Background/History

On March 13th, 2020, Governor Greg Abbott issued a proclamation declaring a state of disaster for all counties in Texas. Since then, HHSC requested the Office of the Governor to suspend certain regulatory requirements and adopted several emergency rules in response to the state of disaster declared in Texas and the United States of America relating to COVID-19. The COVID-19 disaster has affected all aspects of provider operations for an extended period, resulting in numerous questions from providers about how HHSC plans to establish and enforce regulatory compliance during the disaster period.

4.0 Resources

State and federal regulatory waivers, suspensions, guidance, and modifications can be found below:

- CMS Waivers and Recommendations, provided at <https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page>.
- COVID-19 guidance and resources from SAMHSA, provided at <https://www.samhsa.gov/coronavirus>.
- Medication-Assisted Treatment guidance and resources from SAMHSA, provided at <https://www.samhsa.gov/medication-assisted-treatment>.
- COVID-19 guidance from Association for the Treatment of Opioid Dependence, provided at <http://www.aatod.org/advocacy/policy-statements/covid-19-aatods-guidance-for-otps>.
- COVID-19 guidance and resources from the DEA's Diversion Control Division, provided at <https://www.deadiversion.usdoj.gov/coronavirus.html>.
- COVID-19 guidance and resources from the Centers for Disease Control and Prevention (CDC), provided at <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>.
- "Coronavirus Disease 2019 (COVID-19)" web page provided on the Texas Department of State Health Services (DSHS), is provided at <https://www.dshs.texas.gov/coronavirus/>.
- Health Care Facility Regulation's webpage, where providers may review facility regulation-related guidance letters, is provided at

<https://hhs.texas.gov/doing-business-hhs/provider-portals/health-care-facilities-regulation>.

- Professional Licensing and Certification Unit's webpage, where licensed professionals may review professional licensure-related guidance letters, is provided at <https://hhs.texas.gov/doing-business-hhs/licensing-credentialing-regulation/professional-licensing-certification-unit>.
- State waivers, provided at <https://hhs.texas.gov/services/health/coronavirus-covid-19/coronavirus-covid-19-provider-information>.
- Governor Greg Abbott's Disaster Proclamation, provided at https://gov.texas.gov/uploads/files/press/DISASTER_covid19_disaster_proclamation_IMAGE_03-13-2020.pdf.
- To receive future updates, sign up for GovDelivery at <https://service.govdelivery.com/accounts/TXHHSC/subscriber/new>.

5.0 Contact Information

If you have any questions about this letter, please contact the Policy, Rules, and Training Section by email at: HCQ_PRT@hhsc.state.tx.us.