

MANATT HEALTH / LIFE SCIENCES

# Navigating COVID-19: Top Issues for Life Sciences

In the midst of the COVID-19 pandemic, life science companies have responded quickly with two vaccines approved in 2020 through emergency use authorization (EUA) and others in late stage clinical trial development through Operation Warp Speed. Likewise, several drugs have received approval for treatment of COVID-19. Whether it is leveraging existing inline products, repurposing compounds, creating new antibodies to fight the disease, developing vaccines, developing diagnostic tests, manufacturing ventilators, producing new home monitoring solutions or developing predictive analytic software to aid in managing intensive care units (ICUs), the life sciences sector has innovated to address the public health emergency in unprecedented ways. Manatt Health is uniquely positioned to guide life sciences companies through a shifting healthcare environment, including helping them understand and navigate emerging coverage, payment, regulatory and operational complexities.

## Key Issues to Consider

### Understanding Coverage and Payment for COVID-19 Treatments and Vaccines

**The Issue:** In response to the pandemic, major government and private payer coverage and payment policies are rapidly evolving. Understanding the shifting coverage and payment landscape during the public health emergency (PHE) and beyond will be critical as new products enter the market.

**How Manatt Can Help:** Manatt supports life sciences companies working on COVID-19 treatments by analyzing Medicare, Medicaid and/or commercial payer coverage and payment policies for products in development across multiple patient settings of care: hospital inpatient (e.g., Medicare MS-DRG payments in the current COVID-19 modified environment), hospital outpatient, physicians' offices and home settings.

### Assessing the Implications of Pricing Inline Products for COVID-19 Treatment

**The Issue:** When a commercial product is already being marketed for one or more indications, companies must understand the issues in pricing that existing drug as a newly approved COVID-19 treatment.

**How Manatt Can Help:** Manatt's interdisciplinary team will probe pricing guardrails and evaluate the potential opportunities and challenges posed by various pricing options, including analyzing the potential implications of average sales price (ASP), Medicaid best price and anti-kickback statute.

### Analyzing the Complexities of Shifting Patients to Home Settings

**The Issue:** At-risk and quarantined patients who need drugs that must be administered in-office by healthcare providers (HCPs) are challenged during this crisis, which is exacerbated by access to many physicians' offices. Therefore, both providers and patients want to enable access to medically necessary HCP-administered drugs at home.

**How Manatt Can Help:** Manatt helps clients understand and navigate the statutory, regulatory, coverage and payment complexities of shifting patient treatment from the physician's office to a home setting.

## Examining and Clarifying Changes in Copay Program Eligibility

**The Issue:** With many Americans facing the loss of both their jobs and their health insurance, access to needed medications is threatened.

**How Manatt Can Help:** Manatt analyzes and summarizes representative companies' copay program eligibility changes in response to COVID-19 to help life sciences companies understand and respond to emerging access challenges.

## Identifying Opportunities to Improve Medication Access

**The Issue:** The pandemic and its economic fallout will create opportunities for regulatory and legislative action to improve medication access.

**How Manatt Can Help:** Manatt develops innovative proposals for improving patient access in the context of high unemployment; economic distress; and healthcare market changes, including new sites of care and new prescriber flexibilities.

## Seeking Food and Drug Administration (FDA) Authorization for Technologies Used to Respond to COVID-19

**The Issue:** FDA regulatory requirements for new Emergency Use Authorization (EUA) requests and new guidance documents that allow companies to make certain changes and introduce new functionalities are rapidly evolving. Understanding these policies as they emerge is crucial to companies seeking to address the important unmet needs that the crisis presents.

**How Manatt Can Help:** Manatt supports EUA requests for ventilators and diagnostic tests, assists companies in understanding FDA's new guidance documents, and supports clients seeking expedited marketing authorization for new technologies outside the EUA process.

## Mapping a Shifting Health Insurance Coverage Landscape

**The Issue:** As record-high unemployment and a shrinking job market drive a growing number of Americans into the ranks of the uninsured, we are likely to see significant shifts in the health insurance landscape.

**How Manatt Can Help:** Manatt analyzes changes in health insurance coverage status and "payer mix," guiding life sciences companies in anticipating, understanding and responding to the implications of a shifting environment.

## We're Here to Help:



**Helen Pfister**  
Leader  
hpfister@  
manatt.com  
212.830.7277



**Sandy Robinson**  
Leader  
swrobinson@  
manatt.com  
202.585.6618



**Anthony Fiori**  
afiori@  
manatt.com  
212.790.4582



**Michael Kolber**  
mkolber@  
manatt.com  
212.790.4568



**Ian Spatz**  
ispatz@  
manatt.com  
310.312.4339