ML STRATEGIES

COVID-19 Insights Week In Review — April 3, 2020

April 03, 2020 | Article |

As the coronavirus pandemic spreads across the nation, your team at ML Strategies continues to monitor legislative and regulatory updates at the **federal** and **state** level. Each week, ML Strategies will provide weekly updates from Massachusetts and Washington, DC to keep you informed and aware of relief opportunities and guidance for your businesses and companies. If you have any questions, please don't hesitate to reach out to ML Strategies professionals who are closely monitoring developments as they happen.

Our ML Strategies COVID-19 Response Team Leads are available and look forward to hearing from you should you have any questions:

FEDERAL LEAD:
Frank C. Guinta – Senior Vice President

MASSACHUSETTS LEAD:
Steven A. Baddour – Senior Vice President of Government Relations

FEDERAL UPDATE

SBA Paycheck Protection Program

The Small Business Administration (SBA) will begin accepting applications on April 3 for the Paycheck Protection Program created by the Coronavirus Aid, Relief and Economic Security (CARES) Act, otherwise referred to as Phase 3 of the federal response to the COVID-19 pandemic. Funded at $349 billion, the Paycheck Protection Program was created for small businesses with fewer than 500 employees (including sole proprietorships, independent contractors and self-employed persons), private non-profit organization or 501(c)(19) veterans organizations affected by coronavirus/COVID-19. There are certain allowances for businesses with more than 500 employees. Applications can be submitted through any SBA 7(a) lender or federally insured depository institution, federally insured credit union, or participating Farm Credit System institution. Applications will be accepted through June 30, although widespread interest in the program is expected so ML Strategies encourages any business interested in the program to apply as soon as possible. Loans made through the program are eligible for full forgiveness if the funds are used for payroll costs, interest on mortgages, rent, and utilities.

Federal Funding & Regulatory Support For COVID-19 Treatments

Billions of dollars of federal funding appropriated for developing COVID-19 medical products (drugs, vaccines, and devices) are being administered through the Biomedical Advanced Research and Development Authority (BARDA). There is a four-step process to request funding and BARDA is generally looking for information to support that a requestor has the capability to manufacture a safe medical product that has a reasonable likelihood of success.

In addition to automobile manufacturers turning to ventilator manufacturing, we are also seeing textile companies look to manufacture personal protective equipment (PPE; e.g., masks and gowns). In the life sciences realm, drug and biologic manufacturers are also considering whether their candidates could be used to treat, mitigate, or prevent some of the effects of COVID-19.

ML Strategies has helped clients shape regulatory and funding submissions and elevated client projects and activities to the highest levels of the federal government, including the White House. In addition to providing funding for trials and medical product manufacturing, the Administration has removed some regulatory barriers to getting products to the market. ML Strategies has been working directly with our contacts at FDA to help them shape policies related to exercising enforcement discretion (i.e., not enforcing certain requirements of the law during the public health emergency) and otherwise adopting more flexible authorization standards for certain products.

IRS Guidance On Tax Credits For Paid Leave

The IRS has posted and overview and FAQs for the COVID-19-related tax credits for required leave provided by small and mid-sized business in the Families First Coronavirus Response Act (FFCRA) – otherwise referred to as Phase 2 of the federal response to the pandemic. The FFCRA provides these employers refundable tax credits that reimburse them, dollar-for-dollar, for the cost of providing paid sick and family leave wages to their employees for leave related to COVID-19.
Read the overview and FAQs here...

IRS Launches Employee Retention Credit

The CARES Act created the Employee Retention Credit to enable employers to keep their employees on the payroll during the pandemic. The refundable tax credit is 50% of up to $10,000 in wages paid by an eligible employer whose business has been financially impacted by COVID-19. On March 31, the IRS released guidance on eligibility and the process for receiving the credit.
Click here for details...

Upcoming Webinar



Everything Life Science Companies Need to Know to Navigate the COVID-19 Pandemic — On Tuesday, April 7, ML Strategies and Mintz will host a webinar on a spectrum of issues companies in the life sciences industry are facing during this complicated period. Topics covered will include Employment Law, FDA, Clinical Trials, Capital Markets, and Federal Legislation.
Learn more and register here...

Recent ML Strategies Washington Insights On COVI

What FDA Has Done So Far In Response to COVID-19 — Mintz Member Joanne Hawana, Senior Director of ML Strategies Aaron Josephson, and Mintz Associate Benjamin Zegarelli co-authored an article published in Law360 discussing the latest actions from the U.S. Food and Drug Administration (FDA) in response to COVID-19.
Read more...

Tackling False Claims Being Made for COVID-19 Treatments and Products — ML Strategies Vice President Christian Tomotsu Fjeld and Senior Director Aaron Josephson join Mintz colleagues in updating on recent developments at the Federal Trade Commission, the Food and Drug Administration, the Department of Health and Human Services, and the Department of Justice related to false or deceptive claims about their products' ability to treat COVID-19.
Read more...

MASSACHUSETTS UPDATE

Federal Support, Procurement/Donation of PPE & COVID-19 Treatment Services

On Monday, March 30th Governor Baker outlined the major steps Massachusetts is making to meet the growing needs of the health care community as positive cases continue to rise in the state. As of Monday, the federal government was set to send 1,400 ventilators to the Commonwealth, which is coupled with $50 million of supplies on order by the Baker Administration for personal protective equipment ("PPE") and other necessary items. In preparation for the anticipated April 7 to April 17 surge, the COVID-19 Response Command Center created a **Command Center Portal** to procure PPE from local manufacturers, as well as accept any donations of supplies hospitals desperately need. From the start of this crisis, Governor Baker has prioritized ensuring the coverage of telehealth services to keep people at home and relieve pressure in already consumed hospitals and urgent care facilities. Residents, however, needed a resource to check symptoms, ask questions and seek assistance. To answer this call, the Baker Administration created an online platform to allow residents to check symptoms and connect to services if needed. **The Buoy platform** is a 24/7 service, free for Massachusetts residents to assist in identifying COVID-19 symptoms and identifying resources and services for concerning cases.

Essential Provider Rates Adjustment

On Tuesday, March 31st the Executive Office of Health and Human Services ("EOHHS") has been authorized by way of COVID-19 Order No. 20 to adjust essential provider rates during the public health emergency. To do so, EOHHS is tasked with designating classes of human services providers determined to be facing increased demand, those necessary to keep vulnerable individuals in their residences to protect against added pressure on critical health care providers, and human services providers forced to respond to the unique demands of COVID-19, which has precipitated the need to adjust modalities of service deliveries and the rate structures attributed to these new modalities. EOHHS has been authorized to issue temporary rates and supplemental payments, as well as establish new rate and payment methodologies to reflect these new modalities.
Read the Governor's order here...

MassHealth Coverage and Additional Guidance

MassHealth has issued guidance to ensure members understand they will not lose coverage during this public health emergency. All coverage types and health plans are covering COVID-19 testing and treatment for members exhibiting symptoms and in need of services. As previously mentioned, to ease the pressures on hospitals and urgent care facilities, MassHealth coverage is covering telehealth services for physical and behavioral health when appropriate. Additional guidance has been issued for families and children receiving behavioral health services in their homes. Lastly, during this crisis, MassHealth members may receive early refills for medications, 90 day supplies and medication delivery. Additional information relative to MassHealth coverage during the COVID-19 crisis can be found **here**.

Recent ML Strategies Massachusetts Insights On COVID-19

Read more of ML Strategies and Mintz are saying in our COVID-19 Insights Center:

UPDATED: Massachusetts Mandates Closure of All Non-Essential Businesses Effective Tuesday, March 24th at Noon — Senior Vice President of Government Relations Steven Baddour, Senior Vice President and Compliance Officer Dan Connelly, Vice President Legislative Affairs Caitlin Beresin, Director of Government Relations Kaitlyn Sprague and Manager of Government Relations Taylor Shepherd outline COVID-19 Order No. 13 and additional guidance for Massachusetts businesses.
Read more...

BREAKING NEWS: Governor Baker Extends Non-Essential Business Closures until Monday, May 4th — Senior Vice President of Government Relations Steven Baddour, Senior Vice President and Compliance Officer Dan Connelly, Vice President Legislative Affairs Caitlin Beresin, Director of Government Relations Kaitlyn Sprague and Manager of Government Relations Taylor Shepherd outline the Baker Administration's extension on non-essential business closures, restrictions on gatherings with ten or more people and school and non-emergency childcare programs.
Read more...

Massachusetts: Corporate Board of Directors and Shareholders Meetings Changes as a Result of COVID-1
— Senior Vice President of Government Relations Steven Baddour, Senior Vice President and Compliance Officer Dan Connelly, Vice President Legislative Affairs Caitlin Beresin, Director of Government Relations Kaitlyn Sprague and Manager of Government Relations Taylor Shepherd highlight COVID-
Order No. 19, which allows publicly traded companies to hold remote shareholder meetings.
Read more...

Authors