

Coronavirus Flash Update: Wednesday, March 25, 2020

The Latest News

- U.S. COVID-19 cases exceed 52,225 and 728 U.S. deaths. (Source: CDC)
- U.S. stock market: Tuesday ended with the single biggest point gain in the Dow's history, gaining over 2,000 points during the day, with S&P 500 up over 200 points and the Nasdaq gaining over 550 points.
- On Monday, the Federal Reserve <u>committed</u> to using its full range of tools to support households, businesses, and the U.S. economy overall in this challenging time.
- On Tuesday, the **Department of Labor (DOL)** released its first round of <u>guidance</u> with fact sheets for employers and employees. <u>FAQs</u> are included explaining the changes for paid sick leave and expanded family and medical leave as required by the Families First Coronavirus Response Act passed last week, noting effective date is April 1, 2020.
- **U.S. Army Corp of Engineers** releases <u>draft</u> request for proposals for companies to submit bids with capabilities to convert hotel space to an acute alternate care facility to support treatment for COVID-19 patients.
- On Monday, President Donald Trump released an <u>executive order</u> on price gouging and hoarding of critical Coronavirus supplies.
- The **Department of Health and Human Services (HHS)** Office of Inspector General (OIG) has posted a fraud alert <u>video</u> to educate the public about scammers offering COVID-19 tests in exchange for personal details of Medicare beneficiaries.
- President Trump invoked the <u>Defense Production Act</u> on March 18 to prioritize and expand the nation's ability to produce key medical supplies such as ventilators and personal protective equipment. For those wanting to understand the Act, read this A&B <u>blog</u>.
 - During Tuesday's White House briefing, the President stated that because of the outpouring of support from the private sector, there has "not been immediate need to use DPA" to increase medical supply procurement and allocation.

Emergency Funding/Supplemental/Stimulus Legislation

- Very early this morning, the President and congressional leaders struck a bipartisan deal on a third bill, informally called "3.0 or stimulus" and officially called the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The rescue financial package, totaling more than \$2 trillion, will provide assistance to many stakeholders seriously impacted by COVID-19, including businesses, health care providers, and most Americans. It includes language to expand unemployment benefits, provide additional funding for state and local governments, assistance for small businesses struggling to make payroll, and funds for hospitals, health centers, and other providers to address the surge in patients due to coronavirus.
 - The details are just coming out, but a near final bill text is available <u>here</u>.
 - The Senate convenes at noon today to begin their consideration of the package and the House is expected to consider it soon after Senate completion by unanimous consent. The President is expected to quickly sign the bill following congressional passage.

- On Tuesday, as final negotiations were underway to complete the CARES Act, discussions began on a fourth (4.0) bill which may include technical corrections for previously passed emergency response bills, and additional emerging needs related to COVID-19.
- The House of Representatives considers its voting <u>options</u> when not actually "present" during the coronavirus pandemic.
- Congress has already passed two bills in the past two weeks:
 - The first bill, the Coronavirus Preparedness and Response Supplemental (CPPRS) (H.R. 6074), which included \$8.3 billion in emergency supplemental funds for key federal agencies responding to the coronavirus epidemic, passed on March 5.
 - The second bill, the Families First Coronavirus Response Act (FFCRA) (H.R.6201), primarily seeks to mitigate the impact on individuals with provisions on low-income food/nutrition assistance, unemployment insurance, emergency leave, and employer tax credits to partially offset the costs of required leave.

Key Administrative and Regulatory Actions

Legal and Financial Issues

- On March 13, President Trump <u>declared</u> a national emergency under the Stafford Act, which allows the federal government to marshal additional resources and authorize greater regulatory flexibility to respond to the coronavirus outbreak.
- In a joint <u>statement</u>, the **federal financial institution regulatory agencies** and state banking regulators encouraged financial institutions to work constructively with borrowers affected by COVID-19 and provided additional information regarding loan modifications.
 - To understand the federal regulators guidance on loan modifications and reporting, see this A&B <u>advisory</u>.
- COVID-19 has had significant impact on business planning, and the **Financial Industry Regulatory Authority (FINRA)** published guidance for its broker-dealer members regarding the impact. For the full analysis read this <u>advisory</u>.
- The Federal Financial Institutions Examination Council (FFIEC) issued updated <u>guidance</u> specific to pandemic planning.
- Last Friday, the Commodity Futures Trading Commission (CFTC) issued a no-action letter offering temporary relief to commodity pool operators (CPOs) from certain obligations under the Commodity Exchange Act and CFTC regulations. A deeper dive on whether this guidance to allow commodity pool operators to delay their reporting obligations during the coronavirus pandemic can be found <u>here</u>.
- On March 18, the **U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB)** <u>issued</u> tax exemption for production of hand sanitizers by distilled spirit permittees.
- Internal Revenue Service (IRS) Notice 2020-17 Extending the time for income tax payments: The Treasury Department and IRS have extended the due date for federal income tax payments due April 15, 2020, to July 15, 2020, for payments due up to \$10 million for corporations and up to \$1 million for individuals—regardless of filing status—and other unincorporated entities. Associated interest, additions to tax, and penalties for late payment are also suspended until July 15, 2020.

- On Tuesday, House Ways and Means Committee Chairman <u>called</u> on the Department of Treasury Secretary Steven Mnuchin to provide an update on the coronavirus impact on tax season.
- The IRS has issued the following tax season guidance:
 - Coronavirus <u>Tax Relief</u>.
 - IRS Operations During COVID-19: Functions continue guidance.
 - Filing and payment deadlines <u>FAQs</u>.
- The **Department of Commerce (DOC)**, Bureau of Industry and Security posted a statement describing the structure of the Defense Priorities and Allocations System (DPAS) and the authority delegated to other agencies. The statement links to a <u>DPAS training Course</u> to assist a company that receives priority rated contracts, subcontracts, or purchase order from the U.S. Government or its contractors.
- The **Federal Emergency Management Agency (FEMA)** provides <u>guidance</u> to companies seeking to import or manufacture medical products to the COVID-19 response.
 - A list of FEMA <u>regional private sector contacts</u> and <u>state contacts</u> can be found here.
- The Department of Justice (DOJ) Antitrust Division and Federal Trade Commission (FTC) announced on March 24, 2020, they will be expediting their usual antitrust business review letter/informal opinion process on competitor collaborations to be done within 7 days (as opposed to the usual many months) of submission of information. It will be available to entities proposing to collaborate on public health projects responding to the virus, including health care providers and other suppliers of relevant goods and services. Relevant legal standards don't change and the review does not provide immunity, but these antitrust reviews can give comfort to participants the government does not intend to prosecute them and can help defend against any subsequent private litigation.
 - Coronavirus challenges grow for companies responding to issues like the new expedited government review process. For practical advice on **avoiding antitrust risk**, review this A&B <u>advisory</u>.
 - The DOJ released a <u>statement</u> noting that the department is prepared to pursue "bad actors" who take advantage of the COVID-19 crisis.
 - On Sunday, the DOJ filed its first <u>enforcement action</u> against COVID-19 fraud, successfully obtaining a temporary restraining order against the operators of the website, "coronavirusmedicalkit.com." The site claimed to be distributing vaccines for a \$4.95 shipping fee, though no known vaccine is effective against COVID-19. The complaint was filed in the Western District of Texas by the DOJ's Civil Division.
 - Federal antitrust agencies to extend merger reviews. On March 17, the DOJ announced it will be asking some merging parties to voluntarily grant the DOJ an additional 30 days to investigate. This comes one day after the director of the Federal Trade Commission's (FTC) Bureau of Competition posted a notice explaining that parties should expect the FTC to reach out to discuss "appropriate modifications of statutory or agreed-to timing arrangements" in its antitrust investigations, while reserving the right to seek court relief if extensions are not provided. Also on March 17, the agencies began receiving federal pre-merger notification (Hart-Scott-Rodino Act) filings exclusively via electronic submission and announced that no "early terminations" will be granted until further

notice. Therefore, even transactions that don't pose significant antitrust concerns cannot close before the expiration of the full statutory waiting period (typically 30 days).

- Understanding how federal agencies will review merger transactions during the coronavirus outbreak has business and legal implications. The A&B Mergers & Acquisitions Group <u>examines</u> what you need to know.
- **Mortgage-backed and asset-backed securities** are beginning to feel the impact of the coronavirus outbreak. To understand the basic disclosure and diligence issues to consider with any securitization, read this <u>advisory</u>.
- The **Securities and Exchange Commission (SEC)** issued an <u>order</u> giving relief to some companies that cannot timely file their reports due to concerns, including the need to update risk disclosures in response to business threats.
 - The SEC released staff guidance two weeks ago to assist issuers' compliance with federal proxy and annual meeting rules. Additional detail and analysis is provided in this A&B <u>advisory</u>.
- Securities litigation is likely to be impacted by the coronavirus and is reviewed in this A&B advisory.
 - One securities class action lawsuit has already been filed against Norwegian cruise lines, its CEO, and its CFO, as shareholders allege the company made false and misleading statements regarding the impact of the coronavirus and the company's focus on customer safety during the outbreak of the coronavirus pandemic.
 - For the many firm clients that have experienced sharp stock price drops in recent days, the C-level management and board members will be concerned about their personal liability. One important thing for them to consider is the scope of D&O insurance coverage for potential shareholder lawsuits, and we regularly assist clients in evaluating that coverage.
- **Commercial Property Insurance**: Some state lawmakers are seeking alternative routes around existing commercial property insurance terms, which generally do not provide business interruption or civil authority coverage where businesses have been impacted by the pandemic and related Stay-At-Home orders and social distancing guidelines.
 - On March 16, New Jersey lawmakers introduced bill <u>A-3844</u>, which purports to require insurance carriers to provide coverage for business interruption due to global virus transmission or pandemic, in essence re-writing policy language. Specifically, under the act, all policies provided to insureds with 100 or fewer full-time employees in the state of New Jersey would be "construed to include among the covered perils under that policy," coverage for business interruption claims arising out of the COVID-19 pandemic. If passed, the bill would apply retroactively to all insurance policies insuring against loss or damage to property in force as of March 9, 2020 (no actions have been taken to date).
 - Congress has also taken an interest in the extent to which commercial property insurance policies will cover COVID-19 related business interruption and civil authority claims. On March 18, a bipartisan group of 18 house members sent a letter to four insurance industry groups asking that they work with their member companies and brokers to recognize financial loss due to COVID-19 as part of policyholders' business interruption coverage. The industry groups have declined to do so noting that business interruption coverage does not, and is not designed to, cover claims relating to pandemics.

 On March 16, Oceana Grill, a popular New Orleans restaurant, filed the first <u>lawsuit</u> against its insurance carrier seeking confirmation that its commercial property insurance policy provides business interruption and civil authority coverage for claims relating to COVID-19.

International Business and Trade

- **Temporary Travel Restrictions** Applicable to **Land Ports of Entry and Ferries Service** between the United States and Canada, United States and Mexico.
 - Customs and Border Protection (CBP) announced the decision of the Secretary of Homeland Security to temporarily limit the travel of individuals from Canada into the United States at land ports of entry along the United States-Canada (See FR notice <u>here</u>), and along the United States-Mexico (See FR notice <u>here</u>) borders, to "essential travel."
- Citing pandemic concerns, **United States Trade Representative (USTR)** invites input on key products hit by **Section 301 tariffs**.
 - In a <u>statement</u> issued late Friday, USTR said it has "opened a <u>docket</u> for members of the public, businesses, and government agencies to submit comments if they believe further modifications to the 301 tariffs may be necessary." The process is designed to supplement, not replace, existing procedures for evaluating requests to exclude products from the tariffs. "Submissions are limited to comments on products subject to the tariff actions and relevant to the medical response to the coronavirus," USTR stated.
- **Transportation and supply chain problems**. A bipartisan group of more than 75 House members sent Trump administration officials a letter last week urging them to "turn to" trading partners to compensate for looming shortages of medical supplies needed to combat the coronavirus outbreak.
 - In a <u>March 20 letter</u>, led by Rep. Cindy Axne (D-IA) and Rep. Troy Balderson (R-OH), lawmakers cited conversations with health care professionals who have expressed concern about a likely "dire shortage" of personal protective equipment for health care providers if the U.S. doesn't take immediate actions.
 - The lawmakers ask the officials to "prioritize working with our trading partners to find essential medical equipment and PPE that is readily available and to avoid placing any new red tape or restrictions on medical providers as they seek to obtain this equipment promptly from available sources."
- Emerging global trade controls restricting exports of critical medical supplies.
 - A Global Trade Alert report says export bans are counterproductive for several reasons, contending that denying foreign buyers medical goods is costly for the practicing country. "Import restrictions on medical supplies reduce the effectiveness of public health interventions. Whatever political calculus led to these import restrictions needs to be revisited and fast," the study says. "Export bans on masks, for example, erode the capability of trading partners to cope with the spread of COVID-19." See the report <u>here</u>.
- General U.S. Government agency operations (Treasury, State, CBP, Commerce and USTR).
 - Information for filing entry information for personal protective equipment and medical devices during COVID-19.

- The U.S. Food and Drug Administration is providing instruction to the import community regarding the submission of entry information for personal protective equipment and certain other devices. Following the instructions will help facilitate the import process for all, especially for products related to COVID-19 public health emergency. See the FDA supplemental <u>guidance</u> for Automated Commercial Environment (ACE).
- With possible disruptions impacting business operations in China and elsewhere, as well as
 disruption for U.S. companies relying on the supply of both component parts and finished goods
 outside the U.S., the question is whether the coronavirus is a force majeure event that will
 excuse their nonperformance. For information see this A&B <u>advisory</u>.
- On March 20, the Organizations for Economic Cooperation and Development (OECD) <u>outlined</u> <u>tax policy</u> steps countries can take to respond to the economic impact of the coronavirus pandemic, including, for example, waiving or delaying payroll-related taxes and employer and self-employed social security contributions, providing tax breaks to health and emergency workers, extending deadlines for tax filing and payments, accelerating tax refunds, deferring estimated payments, liberalizing loss carryforward and carryback provisions.

Workplace & Home Issues

- Government Closure/Stay-at-Home orders released in multiple state and local jurisdictions initially started earlier this week in several California bay area counties. To date, states issuing these orders include <u>California</u>, <u>Connecticut</u>, <u>Delaware</u>, <u>Hawaii</u>, <u>Illinois</u>, <u>Indiana</u>, <u>Kentucky</u>, <u>Louisiana</u>, <u>Massachusetts</u>, <u>Michigan</u>, <u>Nevada</u>, <u>New Jersey</u>, <u>New Mexico</u>, <u>New York</u>, <u>Ohio</u>, <u>Oregon</u>, <u>Pennsylvania</u>, <u>Washington</u>, <u>West Virginia</u>, and <u>Wisconsin</u>.
 - The State of New York has passed a <u>COVID-19 sick leave law</u> requiring paid leave to workers who are subject to an order of mandatory or precautionary quarantine or isolation for COVID-19.
 - For those asking how to define "federal crucial infrastructure sectors" the Department of Homeland Security's Cyber Infrastructures division <u>outlines</u> 16 sectors.
 - These orders challenge business to understand who is an "essential business" and other implications. To understand the business and legal implications, read this A&B <u>advisory</u>.
 - The Council of State Governments provides a <u>website</u> linking to all state orders.
- The **DOL** released a <u>statement</u> which includes an overview of key COVID-19 related DOL and **Occupational Safety and Health Administration (OSHA)** documents which includes:
 - OSHA's practical guidance to prevent the spread of COVID-19
 - OSHA's COVID-19 website
 - Wage and Hour Division (WHD) <u>guidance</u> on Families First Coronavirus Response Act (FFCRA): Employee Paid Leave Rights
 - WHD guidance on FFCRA: Employer Paid Leave Requirements
 - WHD FAQs on COVID-19 and the Fair Labor Standards Act
 - WHD <u>FAQs</u> on COVID-19 and the Family and Medical Leave Act
 - Trying to make sense of all these changes? A&B provides brief overviews of what you need to know:
 - Coronavirus Impact on Health Benefits: <u>A Deeper Dive</u>

- o Employee Leave Requirements Under FFCRA advisory
- COVID-19 <u>FAQs</u> for Employers
- Employers and employees considering domestic travel decisions can find information in this A&B <u>advisory</u>.
- **Cyberhygeine** has become a focus in the workplace and for those working from home, <u>here</u> are six practical tips to stay protected while working from home during the coronavirus outbreak.
- The **construction industry** is confronting multiple coronavirus related crises. To understand the trends read this A&B <u>advisory</u> on the five best practices.
 - **Construction contracts**: The availability of force majeure and other related doctrines to excuse contractual performance is examined <u>here</u>.
- Last week, the **Cybersecurity and Infrastructure Security Agency (CISA)** released <u>guidance</u> to help state and local jurisdictions and the private sector identify and manage their essential workforce while responding to COVID-19.
- Environmental Protection Agency (EPA) has identified <u>274 disinfectant products</u> that can be used against SARS-CoV-2 (the cause of COVID-19). Some products kill the virus in 15 seconds while others require at least 10 minutes.
 - EPA created a website, <u>Coronavirus and Drinking Water and Wastewater</u>, which states that the risk to water supplies from the COVID-19 virus is low, and "Americans can continue to use and drink water from their tap as usual."
- Occupational Safety and Health Administration (OSHA) updated its <u>website</u>, clarifying that no special precautions (beyond existing requirements) are required for municipal solid waste and recycling suspected or known to contain or be contaminated with COVID-19.
- Large employers are assessing policies and potential liability to ensure a safe and secure workplace. The **CDC** has <u>released</u> guidance for employers related to employee information on COVID-19.
- Federal Motor Carrier Safety Administration (FMCSA) has exempted waste haulers from hoursof-service (HOS) regulations in its Expanded Emergency Declaration.
 - Restrictions have also been lifted in states such as AL, MA, and TX.
- The Healthcare Waste Institute (HWI) of the National Waste & Recycling Association (NWRA) has asked states to grant flexibility for Regulated Medical Waste (RMW) handling to extend maximum storage times at health care and treatment facilities and allow storage of large quantities at treatment facilities.
 - Florida is allowing extended hours for permitted medical waste facilities and can grant waivers for storage times and tonnage limits, upon request.
- The NWRA asked the **Federal Highway Administration (FHWA)** to issue guidance to states to allow hauling of extra heavy loads of COVID-19 waste via special permits.
 - States including MD, NE, ND, TN, and VA have lifted weight restrictions for overweight trucks transporting waste. States including AL, CA, CT, IA, KY, OK, and TN have issued extensions on Commercial Drivers Licenses (CDLs).



Cyber Security & Privacy

- Governments are increasingly seeking to leverage consumer geolocation data collected by industry as a tool to assist with fighting the spread of COVID-19. To see how the U.S. compares with the rest of the world, read this post on our <u>Privacy and Security Blog</u>.
- NIST's Information Technology Library published a bulletin titled <u>Security for Enterprise</u> <u>Telework, Remote Access, and Bring Your Own Device (BYOD) Solutions.</u> This document summarizes NIST Special Publication 800-46 Revision 2 and is a helpful guide for companies wrestling with a newly remote workforce.
- With cybersecurity, there's more than a virus in the air— there's malware and spyware too. To better understand the proactive steps Health Insurance Privacy and Accountability Act (HIPAA) covered entities and business associates can take to protect their systems and their clients' information during the coronavirus pandemic, read this A&B <u>advisory</u>.
- The expanded use of working from home using remote access resources has companies increasing the need to guard against cybersecurity threats. For an overview of issues to consider and prepare for, visit <u>COVID-19 and Cyber</u>.

Health Care/Human Services

- On Tuesday, the **HHS** <u>announced</u> \$250 million in grants for meal programs for older adults. The program is administered through the **Administration of Community Living (ACL)**, and funding was provided through the FFCRA legislation passed by Congress last week.
- The **U.S. Citizenship and Immigration Services** posted an <u>announcement</u> clarifying that any treatment or preventive services related to COVID-19 <u>will not</u> negatively affect any individual as part of a future Public Charge analysis.
- The **Occupational Safety and Health Administration (OSHA)** is providing this temporary <u>guidance</u> regarding required annual fit-testing allowing enforcement discretion, which is to take effect from the date of this memorandum and remain in effect until further notice.
- Health care **providers with exposure to COVID-19** raises numerous serious questions and to better understand these considerations for health care workers and their employees, read this A&B <u>advisory</u>.
- **Centers for Medicare & Medicaid Services (CMS)** has created a <u>website location</u> for COVID-19 Stakeholder call recordings and transcripts.
- CMS has created a <u>website</u> for all coronavirus related documents, including the CMS national emergency <u>guidance</u>. Several new items this past week include:
 - Yesterday, CMS released <u>guidance</u> implementing provisions of the FFCRA that provide states with enhanced federal Medicaid funding referred to as the Federal Medical Assistance Percentage (FMAP) funding during the COVID-19 emergency.
 - On Sunday, CMS <u>announced</u> relief for providers participating in quality reporting programs, including granting exceptions from reporting requirements and extensions for clinicians and providers participating in Medicare quality reporting programs for the upcoming measure and data submission for those programs. The release includes tables listing the impacted programs and extensions.

- **Waivers**: Further information continues to be released on blanket waivers after the initial <u>guidance</u> on March 13 response to the national emergency executive order.
 - On Sunday, March 22, CMS issued provider enrollment FAQs for 1135 blanket waiver, available <u>here</u>. In addition, there is an FAQ on telehealth services (Q11) and requirements if a practitioner seeks to furnish Medicare telehealth services from his or her home.
 - An A&B<u>advisory</u> on the section 1135 waivers provides background, how to request them, EMTALA considerations, overview of Medicaid and CHIP 1135 waivers, and guidance for health care providers and suppliers.
 - Early last week, CMS approved its first 1135 waivers in <u>Florida</u> and <u>Washington</u>. CMS has posted a <u>toolkit</u> on 1135 waivers.
 - On Monday, CMS announced 11 additional states approved for 1135 waivers: <u>Alabama</u>, <u>Arizona</u>, <u>California</u>, <u>Illinois</u>, <u>Louisiana</u>, <u>Mississippi</u>, <u>New Hampshire</u>, <u>New Jersey</u>, <u>New Mexico</u>, <u>North Carolina</u>, and <u>Virginia</u>.
- A snapshot of some **submitted waivers**:
 - California 1135 waiver (3/16);
 - Illinois 1135 <u>waiver</u> request (3/19): Illinois Hospital Association <u>waiver</u> request (3/20);
 - Massachusetts 1135 <u>waiver</u> request (3/20);
 - Mississippi 1135 <u>waiver</u> request (3/18) [side note: MS emergency telehealth policy: <u>waiver</u>];
 - North Carolina 1135 <u>waiver</u> request(3/17);
 - North Dakota 1135 <u>waiver</u> request (3/18);
 - New Hampshire 1135 waiver request (3/18); and
 - South Dakota 1135 <u>waiver</u> request (3/19).
- CMS released <u>recommendations</u> last week on adult elective surgeries and nonessential procedures. This <u>release</u> provides details including that decisions will be made at the local level by the clinician, patient, hospital, and state and local health departments.
- On March 19, CMS <u>announced</u> that the implementation of the Minimum Data Set 3.0 v1.181 for **nursing home and swing bed providers** set for October 1, 2020 was now delayed.
- To clarify COVID-19 coverage for the diagnosis and treatment, CMS released FAQs on Catastrophic Health Coverage; the agency states that it will not bring enforcement action against any health issuer that amends its catastrophic plans to provide coverage without imposing cost-sharing requirements for COVID-19 related services before an enrollee meets the catastrophic plan's deductible. CMS also notes that the use of enforcement discretion and the FAQs issued align with the IRS guidance released which provides flexibility to high deductible plans to provide COVID-19 health benefits without applying a deductible or cost-sharing.
- New telehealth <u>guidance</u> was announced last week broadening access to Medicare telehealth service regardless of patient residence and covering a wide range of services. The telehealth waiver has been expanded; states can cover telehealth

without approval, and HIPAA rules will be relaxed, and penalties waived. Factsheets related to these changes:

- o CMS telehealth FAQs
- o HHS 1135 HIPAA waiver <u>factsheet</u>
- HHS Notice of Enforcement Discretion <u>factsheet</u>
- o HHS Office of Civil Rights bulletin
- o <u>Guidance</u> on Business Associate Agreements
- HIPAA Security Rule <u>safeguards</u>
- On Sunday, CMS released new <u>tools</u> for state Medicaid and Children's Health Insurance Programs (CHIP) and updated (March 18) <u>FAQs</u>. The tools include:
 - 1115 Waiver Opportunity and Application <u>checklist</u>;
 - 1135 Waiver <u>checklist</u>;
 - 1915(c) Appendix K <u>template</u>; and
 - Medicaid Disaster State Plan Amendment template.
- On March 16, CMS announced steps to improve testing of patients in emergency departments with a <u>memorandum</u> for Medicare participating hospitals, and the agency released a <u>factsheet</u> on telehealth benefits for Medicare beneficiaries. CMS also released a <u>memorandum</u> regarding EMTALA, allowing for alternative testing sites and other guidance.
- CMS released new guidance last week on nursing home patients and visitors.
 - CMS <u>announced</u> on Monday, it will limit its **nursing home inspection** protocol to focus more specifically on complaint and infection control inspections.
- Last week, CMS released <u>guidance</u> to Program of All-Inclusive Care for the Elderly (PACE) Organizations.
- Information and <u>FAQs</u> for individuals, issuers, and states on COVID-19 health coverage benefits.
- <u>Guidance</u> for health care workers on protective masks. This release included a <u>memorandum</u> to state survey agencies who inspect nursing homes and other health care post-acute and acute facilities.
- o <u>Guidance</u> regarding health care workers in home health agencies and dialysis centers.
- CMS issued <u>guidance</u> to help Medicare Advantage and Medicare Part D plans respond to COVID-19.
- The Department of Health and Human Services (HHS) Office of the Assistant Secretary of Preparedness and Response (ASPR) <u>announced</u> on March 9 that a diagnostic test for COVID-19 was nearing completion and would process up to 1,000 tests in 24 hours.
 - On Sunday, the ASPR <u>announced</u> the funding of a phase 2/3 clinical trial in a joint partnership with Regeneron Pharmaceuticals to develop a potential treatment for COVID-19.
- Over the weekend, the **Food and Drug Administration (FDA)** announced that it had issued the first Emergency Use Authorization for Point of Care Diagnostic for the Cepheid Xpert Xpress SARS-CoV-2 test. A copy of the authorization letter can be found <u>here</u>. This follows the Agency granting emergency use authorization (EUA) to two new tests (Hologic and LabCorp), bringing the total number to four (Roche Holding and Thermo Fisher).

- For deeper dive on FDA accelerated approval process for COVID-19 tests, see this <u>Advisory</u>.
- On Tuesday, the FDA <u>announced</u> steps to increase supplies through instruction for PPE and device manufacturers.
- FDA <u>announced</u> on Monday new procedures that will allow the agency to issues all new COVID-19-related guidance without notice to allow for immediate implementation.
- Also on Monday, the FDA <u>announced</u> that while all REMS remain unchanged, the Agency will not pursue enforcement action for accommodations made regarding laboratory testing or imaging study requirements during the emergency.
- FDA established a toll-free hotline (1-888-INFO-FDA) to respond to lab, manufacturers, and health care providers on testing and testing shortages. To aide these inquiries the FDA <u>released</u> FAQs about COVID-19 diagnostic tests. For sponsors wishing to develop therapeutics the FDA encourages submission and questions <u>via</u> <u>the Pre-IND Consultation program</u>.
- On Sunday, the FDA took actions to increase the availability of ventilators and accessories, as well as other respiratory devices, to supporting patients with respiratory failure or difficult breathing through the issuance of <u>enforcement policy</u> for respiratory devices and other accessories.
- FDA issued an immediately in effect <u>guidance</u> for industry and FDA that allows manufacturers of certain FDA-cleared non-invasive, vital-sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate, and blood pressure.
- FDA issued a revised <u>guidance</u> (Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic) to clarify what is applicable to any pandemic, not just an influenza pandemic.
- One week after the FDA announcement that it was postponing most foreign inspections through April, FDA Commissioner Hahn <u>announced</u> last week that the Agency will scale back **domestic** inspections for all FDA-regulated products, including drugs, devices, biological products, foods, animal feed, and tobacco. For a deeper dive on industry considerations to these delays, review these A&B advisories on <u>domestic inspections</u> and <u>foreign inspections</u>.
- Last week the FDA issued, "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic," to assist sponsors in assuring the continued safety of trial participants, while minimizing risks to trial integrity, and maintaining compliance with good clinical practices (GCPs) during the pandemic. Included in the new guidance are the options for phone contact and virtual visits in clinical trials.
- To assist in the conservation of masks and gowns the FDA has provided <u>strategies</u> and added glove conservation <u>strategies</u> on Friday.
- Last week, the FDA <u>announced</u> new authority for states to develop diagnostic tests for COVID-19 so that laboratories will not be required to engage with the FDA and for commercial developers once granted emergency use.

- The FDA acknowledged the growing shortages of personal protective equipment, and an A&B analysis of the agency's FAQs is available <u>here</u>.
- On March 20, the FDA issued a <u>statement</u> that the Agency is beginning to see unauthorized fraudulent test kits that are being marketed to test for COVID-19 in the home. Earlier in March, the FDA and the FTC <u>issued</u> warning letters to seven companies for selling fraudulent COVID-19 products.
- The Health Resources and Service Administration (HRSA) <u>launched</u> an information collection effort last week to support the response to COVID-19 pandemic by surveying HRSA-funded health centers on their response. This information collection effort was initiated pursuant to today's <u>waiver</u> of the Paperwork Reduction Act.
 - On Tuesday, HHS, through HRSA, <u>awards</u> \$100 million to 1,381 health centers across the country with funding provided by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. The awards, by state, is available <u>here</u>.
 - HRSA also <u>announced</u> on Tuesday it was providing \$100 million in awards for health systems to prepare for COVID-19 patients.
- The Centers for Disease Control and Prevention (CDC) released <u>guidance</u> on COVID-19 testing priorities.
 - CDC <u>guidance</u> on Personal Protective Equipment (PPE).
 - On March 18, the CDC released **updated** <u>guidance</u> on strategies for optimizing the use of eye protection, isolation gowns, facemasks, and N95 respirators.
 - The CDC also updated its infection control guidance.
 - Developed new <u>guidance</u> on the use of respirators beyond manufacturer designated shelf life.
 - The CDC's <u>FAQs</u> for health professionals.
 - The CDC's latest guidance on Lab Biosafety Guidelines.

Other News

- The World Health Organization (WHO) provides daily "situation" reports.
- The Joint Commission on Accreditation for Healthcare Organizations (The Joint Commission) announced it was suspending surveying in response to the coronavirus outbreak. The suspension is expected to last through April.

For background and the most up-to-date information, please visit the Centers for Disease Control and Prevention Coronavirus Disease 2019 website: <u>HERE</u>. The additional federal agency links are provided by the White House Coronavirus Task Force:

U.S. Department of Health and Human Services:

- Twitter (<u>here</u>)
- Facebook (<u>here</u>)

Centers for Disease Control and Prevention:

- Twitter (<u>here</u>)
- Facebook (<u>here</u>)

What you should know:

- Workplace, School, and Home Guidance
- People at Risk for Serious Illness from COVID-19
- How COVID-19 Spreads
- <u>Symptoms</u>
- <u>Steps to Prevent Illness</u>
- <u>Testing</u>
- Frequently Asked Questions
- What to Do If You Are Sick with COVID-19
- <u>Stigma Related to COVID-19</u>
- What You Need to Know
- Facts about COVID-19
- Information for People at Higher Risk and Special Populations
- <u>Communication Resources</u>

Situation Updates:

- <u>Situation Summary</u>
- Cases in the U.S.
- Global Locations with COVID-19
- <u>Risk Assessment</u>
- CDC in Action: Preparing Communities

Information for Businesses:

- Interim Guidance for Businesses and Employers
- Information for Communities, Schools, and Businesses
- Environmental Cleaning and Disinfection Recommendations Community Facilities
- SBA: <u>COVID-19 Resources</u>
- DOL: Guidance for Preparing Workplaces for Coronavirus
- DOL: OHSA Resources for Workers and Employers on COVID-19
- WHO: Get Your Workplace Ready for COVID-19
- CISA: <u>Risk Management for COVID-19</u>
- EPA: Disinfectants for Use Against COVID-19
- Federal Reserve: <u>Coronavirus Disease 2019 (COVID-19) Resources</u>.
- FDIC: Coronavirus (COVID-19) Information for Bankers and Consumers.
- OCC: <u>COVID-19 (Coronavirus)</u>.
- Conference of State Bank Supervisors: Information on COVID-19 Coronavirus.
- NYDFS: Coronavirus: Information for Industry and Regulated Entities.
- NMLS: <u>State Agency Communication/Guidance on Coronavirus/COVID-19</u>

Information for Travel and Transportation:

- Information for Travel
- Guidance for Ships

- Guidance for Airlines and Airline Crew
- State: <u>Travel Advisories</u>
- State: <u>Traveler's Checklist</u>
- State: Smart Traveler Enrollment Program
- DOT: FAQs from FTA Grantees Regarding COVID-19

Information for Health Care Providers, First Responders, and Research Facilities:

- Information for Healthcare Professionals
- Resources for State, Local, Territorial and Tribal Health Departments
- <u>Resources for Healthcare Facilities</u>
- Infection Prevention and Control Recommendations for Patients with COVID-19 or Persons Under Investigation in Healthcare Settings
- Information for Laboratories
- <u>Resources for First Responders</u>
- <u>Guidance for Public Health Professionals Managing People with COVID-19 in Home Care and</u> <u>Isolation Who Have Pets or Other Animals</u>
- FAQs and Considerations for Patient Triage, Placement and Hospital Discharge
- <u>What Law Enforcement Personnel Need to Know</u>
- <u>Guidance for Homeless Shelters</u>
- <u>Guidance for Hemodialysis Facilities</u>
- CMS: Information on COVID-19 and Current Emergencies
- CMS: <u>Guidance for Hospice Agencies</u>
- CMS: <u>Emergency Medical Treatment and Labor Act Requirements and Implications Related</u> to COVID-19
- CMS: FAQs for State Survey Agency and Accrediting Organizations
- EPA: Disinfectants for Use Against COVID-19

Information for Families and Households:

- Information on COVID-19 for Pregnant Women and Children
- Interim Guidance for Household Readiness
- Environmental Cleaning and Disinfection Recommendations for U.S. Households
- Guidance for Preventing the Spread of COVID-19 in Homes and Residential Communities
- FAQ: COVID-19 and Children
- EPA: Disinfectants for Use Against COVID-19

Information for Schools and Childcare Providers:

- Interim Guidance for Administrators of U.S. Childcare Programs and K-12 Schools
- <u>Resources for Institutes of Higher Education</u>
- Environmental Cleaning and Disinfection Recommendations Community Facilities
- USDA: USDA Makes It Easier, Safer to Feed Children in California Amid Coronavirus Outbreak
- DOE: <u>Resources for Schools and School Personnel</u>

Information for Community Events and Gatherings:

- Interim Guidance for Mass Gatherings and Large Community Events
- Interim Guidance for Community- and Faith-Based Organizations

Information for Military Response:

• DOD: <u>Department of Defense Coronavirus Response</u>

Alston & Bird Coronavirus Links

- Alston & Bird Coronavirus <u>Task Force</u> Web page
- To Subscribe to Alston & Bird Advisories
- For Alston & Bird <u>COVID-19 Insights and Events</u>
- Previous Alston & Bird Coronavirus Advisories (not included in the above)
 - March 6 <u>Securities Law Advisory: SEC Provides Conditional Relief to Companies Affected</u> by COVID-19
 - March 5 <u>Health Care Advisory: Congress Expands Medicare Telehealth Benefit Amid</u> <u>Coronavirus Concerns</u>
 - **February 28** <u>Labor & Employment / Health Care Advisory: The Coronavirus: Employer</u> and Workplace Considerations
 - **February 21** <u>Litigation Advisory: Does Your Force Majeure Provision Extend to the</u> <u>Coronavirus?</u>