

Coronavirus Flash Update: Friday, March 27, 2020

The Latest News

- U.S. COVID-19 cases exceed 85,381 and 1,271 U.S. deaths. (Source: CDC)
- U.S. stock market: Thursday ended with a third day of gains. The Dow finished up 6.4%, the Nasdaq rose 5.6%, and the S&P 500 closed up 6.2%.
- Congress nears final action on the **largest aid package in U.S. history**, and the pressure for action was evident as the **unemployment claims for last week hit nearly 3.3 million**. The unemployment claims were the largest ever recorded in a single week.
- The Department of Homeland Security <u>announced</u> on Thursday that the deadline to enforce REAL ID requirements would be delayed 12 months to October 1, 2021.

Emergency Funding/Supplemental/Stimulus Legislation

- Late Wednesday night, the U.S. Senate passed H.R. 748, informally called '3.0', by a vote of 96-0 (4 not voting due to quarantine). The House will vote today and is expected to pass, and the President has said he will sign it. The Coronavirus Aid, Relief, and Economic Security (CARES) Act is the third bill in response to the pandemic in 3 weeks. This \$2.2 trillion-dollar package includes \$500 billion in financial assistance for distressed businesses, \$349 billion in low-interest small business loans, and \$100 billion in financial assistance for hospitals. The bill includes \$1,200 in financial assistance for the lowest income taxpayers, an additional 13 weeks of unemployment compensation benefits, and an employee extension credit.
 - o The bill text is available here and a section by section summary is available here.
 - Based on the actions taken after the passage of last week's coronavirus response bill, FFCRA, the federal agencies will be rapidly developing and releasing guidance for the funding provisions enacted – many agencies released guidance earlier this week to implement provisions in FFCRA.
 - Before the President has even put felt tip to paper, discussions for a fourth bill, 4.0, have begun. It may include technical corrections, new areas of need in response to COVID-19 impact, and stakeholder priorities which failed to gain sufficient support to be included in the last bill.
- Congress had already passed two bills in the previous three 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. It was passed on March 18.

Key Administrative and Regulatory Actions

Legal and Financial Issues

- President Trump invoked the <u>Defense Production Act</u> (3/18/20) 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> (3/18/20).
 - 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.
- President Trump <u>declared</u> (3/13/20) 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.

Department of Justice (DOJ)

- On March 23, President Donald Trump released an Executive Order on hoarding and price gouging of critical COVID-19 supplies. For guidance and tips on how businesses can respond if they are victims of price gouging read this A&B advisory.
- DOJ Antitrust Division and Federal Trade Commission (FTC) announced (3/24/20) 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.
 - On March 26, FTC Chairman Joe Simons issued a <u>statement</u> outlining the agency's efforts to protect consumers during the Coronavirus pandemic. Simons also acknowledged the challenges businesses face in getting important goods and services to people across the country, and that the agency would be "flexible and reasonable" in enforcing compliance requirements. He also announced an email address for businesses seeking guidance: business.covid@ftc.gov, noting FTC staff would respond to inquiries as quickly as possible.
 - On March 25, the FTC released <u>business guidance</u> warning against various scams seeking to exploit companies' concerns around COVID-19. Scams the FTC warns against include a variety of robocall and email-related phishing scams (including through emails purporting to come from company CEOs or IT departments, or government agencies), and fraudulent websites that mimic legitimate online retailers. The alert also provides advice on how companies can keep their networks safe.
 - 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 advisory. (3/24/20)

- The DOJ filed its first enforcement action (3/21/20) 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.
- For a deeper dive in how **federal agencies will review merger transactions** during the coronavirus pandemic, read this A&B advisory. (3/19/20)
- o Federal antitrust agencies to extend merger reviews. On March 17, the DOJ announced (3/17/20) 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 (3/16/20) 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 (3/17/20) 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 examines (3/19/20) 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 advisory. (3/17/20)
- The **Securities and Exchange Commission (SEC)** issued an <u>order</u> (3/4/20) 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 advisory. (3/16/20)
- Securities litigation is likely to be impacted by the coronavirus and is reviewed in this A&B advisory. (3/13/20)
 - 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.
- Companies will need to vigilantly monitor inside trading despite the SEC's statements on relaxed disclosure and other regulations. These issues are examined in this A&B <u>advisory</u>.

Department of Treasury (Treasury)

- On Monday, the Federal Reserve <u>committed</u> (3/23/20) to using its full range of tools to support households, businesses, and the U.S. economy overall in this challenging time.
- In a joint <u>statement</u> (3/22/20), 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>. (3/24/20)
- The **U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB)** <u>issued</u> (3/18/20) tax exemption for production of hand sanitizers by distilled spirit permittees.
- 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 advisory. (3/13/20)
- The **Federal Financial Institutions Examination Council (FFIEC)** issued updated <u>guidance</u> (3/6/20) specific to pandemic planning.
- Internal Revenue Service (IRS) granted further COVID-19 emergency relief in Notice 2020-18 (superseding its prior announcement) delaying the due date for filing Federal income tax returns and making Federal income tax payments from April 15, 2020 to July 15, 2020. The deadline is automatically postponed with no need for taxpayers to file Forms 4868 or 7004. Unlike prior guidance, there is no limitation on the amount of tax payments that may be deferred until July 15, 2020. Read here for both guidance and FAQs.
 - On Tuesday, House Ways and Means Committee Chairman <u>called</u> (3/24/20) 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 Tax Relief. (3/13/20)
 - o IRS Operations During COVID-19: Functions continue guidance. (3/24/20)
 - Filing and payment deadlines <u>FAQs</u>. (3/13/20)
- The **Commodity Futures Trading Commission (CFTC)** issued a no-action <u>letter</u> (3/20/20) 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 here. (3/23/20)

Department of Homeland Security (DHS)/Department of Defense (DOD)

- 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</u> <u>private sector contacts</u> and <u>state contacts</u> can be found here.
- The **U.S. Citizenship and Immigration Services** posted an <u>announcement</u> (3/13/20) 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.

• **U.S. Army Corp of Engineers** releases <u>draft</u> (3/23/20) 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.

Department of Commerce (DOC)

- 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.
 - Commercial Property Insurance: Legal actions have begun 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. Lawmakers are responding by looking for alternative routes around existing commercial insurance terms,
 - On March 25, French Laundry Partners, KRM, Inc. and Yountville Food Emporium, LLC, the operators and managing entities for three restaurants in Napa, California filed a joint complaint against Hartford Insurance Company and Trumbull Insurance Company in California state court. Plaintiffs seek a declaratory judgment that the March 18 Stay-At-Home order of the health officer of Napa County triggered coverage under their policy's Civil Authority provisions, and that business losses are otherwise covered losses under the policy because the policy does not exclude losses incurred as a result of a viral pandemic.
 - Oceana Grill, a popular New Orleans restaurant, filed the first <u>lawsuit</u> (3/16/20) 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.
 - On March 24, the Chickasaw Nation Department of Commerce and the Choctaw Nation of Oklahoma each filed separate lawsuits in Oklahoma state court against their property insurers. The Nations seek a declaratory judgment that their insurance policies cover the Nations' business losses and expenses related to the COVID-19 pandemic and infection. These complaints follow the March 16 complaint by Oceana Grill in Louisiana state court.
 - On March 24, Ohio lawmakers followed New Jersey's lead, proposing new <u>legislation</u> that purports to require insurance carriers to provide coverage for business interruption due to global virus transmission or pandemic, essentially re-writing policy language in the absence of an unambiguous exclusion. Like the New Jersey <u>bill</u>, Ohio's proposal is limited to only those policies issued to insureds located in Ohio that employ 100 or fewer employees.
 - A New Jersey lawmakers introduced bill <u>A-3844</u> (3/16/20), 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.
 - Massachusetts lawmakers went a step further than those in New Jersey and Ohio, proposing <u>legislation</u> on March 24 that purports to require that "every policy of insurance insuring against loss or damage to property, notwithstanding the terms

- of such policy" include among its covered perils "coverage for business interruption directly or indirectly resulting from the global pandemic known as COVID-19." The Massachusetts bill further prohibits insurers in Massachusetts from denying a claim for business interruption coverage on grounds that COVID-19 is a virus or because there was no physical damage to property. The Massachusetts bill would apply to insureds with 150 or fewer employees.
- State regulators, including the California Department of Insurance and the New York Department of Financial Services, are directing insurers to submit data regarding coverage of commercial business interruption related to COVID-19 in an effort to assist small businesses in their respective states.

International Business and Trade

- Senate Finance Republicans urge the administration to alleviate COVID-19 harmful impact on trade policy and outlined policies which might be used to combat the economic harm caused by the coronavirus pandemic and are calling for multilateral cooperation and a "total moratorium" on new tariffs. Led by Chairman Chuck Grassley (R-IA), the lawmakers urge President Trump, the U.S. Trade Representative Robert Lighthizer, and other officials to quickly take several actions to "blunt the health and economic impact of COVID-19," according to a March 25 letter.
- Changes in the way European competition authorities will be enforcing the rules during the coronavirus pandemic are examined in this A&B advisory. (3/25/20)
- Transportation and supply chain problems China to seal boarders to most foreigners. China's Civil Aviation Administration announced it will block almost all foreigners from entering the country starting on March 28, a recognition that most new coronavirus cases were coming from overseas now that the government slowed the spread of the disease among its own people.
- General U.S. government agency operations (Treasury, State, Customs and Border Protection, Commerce, and USTR). CBP will no longer take requests to defer payments of customs duties, the agency said in a CSMS message. "CBP will retain the right to allow additional days for narrow circumstances, including a physician inability to file entry or payments, due to technology outages or port closures," the agency said. CBP briefly allowed for such deferral requests due to the COVID-19 outbreak. "Although the temporary option was provided to extend payment due dates, if the money was withdrawn from the account, these funds are legally owed to CBP and a refund will not be issued," it said on March 26. "Trade users need to work with their financial institutions to ensure that future ACH debit and ACH credit payments to CBP are processed appropriately."
- **USTR has** issued another set of product exclusions from the fourth group of Section 301 tariffs on goods from China on March 25. The new exclusions from the tariffs include "five 10-digit HTSUS subheadings and seven specially prepared product descriptions, which together cover 36 separate exclusion requests" according to the notice. The product exclusions apply retroactively to September 1, 2019, the date the fourth set of tariffs took effect. They will remain in effect until September 1, 2020.
 - o For more analysis on the USTR's request for comments to modify Section 301 duties on Chinese products due to the coronavirus pandemic, read this A&B advisory. (3/26/20)

- **G20 Leaders pledged to address trade disruptions caused by COVID-19.** "Emergency measures aimed at protecting health will be targeted, proportionate, transparent, and temporary," G20 leaders said in a joint statement issued after a teleconference. "We commit to continue working together to facilitate international trade and coordinate responses in ways that avoid unnecessary interference with international traffic and trade." The full G20 leaders' March 26 Statement on COVID-19 can be found here.
- 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 advisory. (3/25/20)
- The Organizations for Economic Cooperation and Development (OECD) <u>outlined tax policy</u> (3/20/20) 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>Colorado</u>, <u>Connecticut</u>, <u>Delaware</u>, <u>Hawaii</u>, <u>Idaho</u>, <u>Illinois</u>, <u>Indiana</u>, <u>Kentucky</u>, <u>Louisiana</u>, <u>Massachusetts</u>, <u>Michigan</u>, <u>Minnesota</u>, <u>Nevada</u>, <u>New Hampshire</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>, <u>Wisconsin</u>, and <u>Vermont</u>.
 - The State of New York has passed a <u>COVID-19 sick leave law</u> (3/18/20) 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> (last update 3/24/20) 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> (3/18/20).
 - o The Council of State Governments provides a website linking to all state orders.

Department of Labor (DOL)

• **DOL** posted on March 26 the required employee notice that must be provided by covered employers to their employees regarding the **new paid leave requirements**. The posted <u>page</u> contains the link to the poster itself, as well as a new Q&A that focuses exclusively on guidance about posting the notice, particularly in light of the fact that many employees are working remotely. Covered employers should make sure they get this notice posted appropriately no later than the April 1, 2020 effective date of the new leave requirements.

- DOL released its first round of <u>guidance</u> (3/24/20) with fact sheets for employers and employees. <u>FAQs</u> (3/24/20) 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.
- **DOL** released a <u>statement</u> (3/9/20) which includes an overview of key COVID-19 related DOL and **Occupational Safety and Health Administration (OSHA)** documents which includes:
 - o OSHA's practical guidance (3/21/20) to prevent the spread of COVID-19
 - o OSHA's COVID-19 website (3/20)
 - Wage and Hour Division (WHD) <u>guidance</u> (3/24/20) on Families First Coronavirus Response Act (FFCRA): Employee Paid Leave Rights
 - o WHD guidance (3/24/20) on FFCRA: Employer Paid Leave Requirements
 - o WHD FAQs (3/24/20) on COVID-19 and the Fair Labor Standards Act
 - o WHD FAQs (3/24/20) 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: A Deeper Dive (3/20/20)
 - Employee Leave Requirements Under FFCRA <u>advisory</u> (3/19/20)
 - o COVID-19 FAQs (3/19/20) for Employers
- **DOL/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> (updated 3/21/20) guidance for employers related to employee information on COVID-19.

Other Agencies

- Environmental Protection Agency (EPA) issued an enforcement memo, "<u>COVID-19 Implications</u> for EPA's Enforcement and Compliance Assurance Program" on March 26, detailing the Agency's plan to exercise enforcement discretion for situations related to COVID-19. The policy is retroactive to March 13.
 - EPA will not seek fines and penalties for missed deadlines in routine monitoring, testing, and reporting; settlement agreements; and consent decrees, and for excess emissions, so long as the company documents in detail that it was related to COVID-19 and takes every effort to meet compliance obligations. EPA must be notified of emission exceedances.
 - EPA is allowing hazardous generators to store additional waste onsite, for longer periods of time, without requiring a permit or changing generator status.
 - For animal feeding operations, the inability to transfer animals off-site will not trigger regulation as a CAFO, or a larger-categorized CAFO.
 - EPA may offer "No Action Assurance" to operators of some critical infrastructure facilities, on a case-by-case basis.
 - Public water systems are excluded from this policy.
- EPA also issued a warning to pesticide producers, manufacturers, distributors, and importers
 who claim their products can be used against COVID-19: ensuring companies comply with all



- applicable requirements for pesticide products including prohibitions on false and misleading claims will be the agency's "focus" in order to protect public health.
- On March 26, EPA added 70 new surface disinfectants to EPA's <u>List N: Disinfectants for Use Against SARS-CoV-2</u> (List N), bringing the total number of products on the list to more than 350.
- EPA is <u>allowing</u> manufacturers of disinfectants to obtain certain inert ingredients and inactive ingredients from different suppliers without checking with the agency for approval.
- **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."
- 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.
- **Federal Motor Carrier Safety Administration (FMCSA)** has exempted waste haulers from hours-of-service (HOS) regulations in its Expanded Emergency Declaration.
 - o Restrictions have also been lifted in states such as AL, MA, and TX.
- 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).
- Employers and employees considering **domestic travel** decisions can find information in this A&B <u>advisory</u> (3/10/20).
- The **construction industry** is confronting multiple coronavirus related crises. To understand the trends read this A&B <u>advisory</u> (3/19/20) on the five best practices.
 - Construction contracts: The availability of force majeure and other related doctrines to excuse contractual performance is examined here (3/23/20).

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 Privacy and Security Blog (3/23/20).
- The Cybersecurity and Infrastructure Security Agency (CISA) released guidance (3/19/20) to help state and local jurisdictions and the private sector identify and manage their essential workforce while responding to COVID-19.
- 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> (3/18/20). This
 document summarizes NIST Special Publication 800-46 Revision 2 and is a helpful guide for
 companies wrestling with a newly remote workforce.



- **Cyberhygeine** has become a focus in the workplace and for those working from home, <u>here</u> (3/18/20) are six practical tips to stay protected while working from home during the coronavirus outbreak.
- 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 advisory (3/16/20).
- 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 COVID-19 and Cyber (3/16/20).

Health Care/Human Services

Department of Health and Human Services (HHS)

- On March 25, pursuant to the President's <u>Executive Order</u>, HHS announced its initial <u>list</u> of health and medical resources that are subject to hoarding prevention measures. The list is subject to review and potential additions later. It includes several varieties of facial masks and other protective equipment, respirators, ventilators, drugs, and disinfectants.
- Tuesday, the **HHS** <u>announced</u> (3/24/20) \$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.
- **HHS** Office of Inspector General (OIG) has posted a fraud alert <u>video</u> (3/23/20) to educate the public about scammers offering COVID-19 tests in exchange for personal details of Medicare beneficiaries.

HHS/Assistant Secretary for Preparedness and Response (ASPR)

ASPR <u>announced</u> (3/24/20) it was providing \$100 million in awards for health systems to prepare for COVID-19 patients.

- On March 22, 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.
- On Sunday, the ASPR <u>announced</u> (3/22/20) the funding of a phase 2/3 clinical trial in a joint partnership with Regeneron Pharmaceuticals to develop a potential treatment for COVID-19.
- ASPR <u>announced</u> (3/9/20) that a diagnostic test for COVID-19 was nearing completion and would process up to 1,000 tests in 24 hours.

HHS/Centers for Disease Control and Prevention (CDC)

- On March 25, the CDC published two preparedness checklists one for <u>healthcare professionals</u> and one for <u>hospitals</u>.
- The CDC released guidance for COVID-19 and Persons with HIV (3/18/20)
- The CDC released <u>guidance</u> (updated 3/24/20) on COVID-19 testing priorities. Priority 1 is limited to hospitalized patients and symptomatic workers. Priority 2 is limited to symptomatic person who live in nursing facilities, are 65 or older, have underlying medical conditions or are first responders.
 - o The CDC also updated its infection control guidance.
 - The CDC's FAQs (3/22/20) for health professionals.
 - The CDC released **updated** guidance (3/18/20) on strategies for optimizing the use of eye protection, isolation gowns, facemasks, and N95 respirators.
 - o The CDC's latest guidance (3/18/20) on Lab Biosafety Guidelines.
 - o CDC guidance (3/10/20) on Personal Protective Equipment (PPE).
 - Developed new <u>guidance</u> (2/28/20) on the use of respirators beyond manufacturer designated shelf life.

HHS/Centers for Medicare & Medicaid Services (CMS)

- **CMS** has created a <u>website location</u> for COVID-19 **Stakeholder call recordings and transcripts**, and daily CMS COVID-19 news alerts can be found here.
- The CMS **Center for Clinical Standards and Quality (CCSQ)** issued a <u>memorandum</u> (3/26/20) stating that under the **Clinical Laboratory Improvement Act (CLIA)** the agency would allow laboratories to utilize temporary testing sites, such as the pathologist's home, for remote review and reporting of slides/images as long as specific criteria are met.
- The National Uniform Billing Committee has provided <u>guidance</u> on claims for COVID-19 treatment and approved the use of DR (disaster related) condition code for services related to the coronavirus.
- CMS released several other alerts and guidance the week of March 23:
 - o Medicare Provider Enrollment Relief FAQs (see: FAQs).
 - CMS posted guidance on Payment and Grace Period Flexibilities for issuers offering coverage on the Federally-facilitated Exchanges and State-based Exchanges on the Federal platform (see: guidance).
 - CMS announced it will be exercising enforcement discretion so QHP issuers and SADPs can
 extend payment deadlines for initial binder payments and ongoing premium payments. CMS
 released FAQs on availability and usage of telehealth through private health insurance (see:
 FAQs).
 - CMS released FAQs on prescription drugs and COVID-19 for health insurance issuers in individual and small group markets (see: <u>FAQs</u>).
- On March 25, CMS <u>announced</u> it did not have the authority to waive Open Payment reporting requirements and the March 31 deadline remains in place.
- CMS has created a <u>website</u> for all coronavirus related documents, including the CMS national emergency <u>guidance</u> (3/13/20).

- On March 24, CMS posted notice that it had <u>withdrawn</u> its proposal rule to tighten Medicaid eligibility determination.
- Yesterday, CMS released <u>guidance</u> (3/24/20) 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.
- CMS released new <u>tools</u> (3/20/20) for state **Medicaid and Children's Health Insurance Programs** (CHIP) and updated (March 18) FAQs (3/18/20). The tools include:
 - 1115 Waiver Opportunity and Application checklist;
 - 1135 Medicaid and CHIP Waiver checklist;
 - 1915(c) Appendix K template; and
 - Medicaid Disaster State Plan Amendment <u>template</u>.
 - Waivers: Further information continues to be released on blanket waivers after the initial guidance (3/13/20) response to the national emergency executive order.
 - CMS issued provider enrollment FAQs for 1135 blanket waiver, available here
 (3/22/20). 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> (3/18/20) 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.
 - CMS has approved 39 states for coronavirus 1135 waivers and for more details and the full list CMS approved 1135 waivers can be found here.

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 waiver request (3/20);
- Mississippi 1135 <u>waiver</u> request (3/18) [side note: MS emergency telehealth policy: waiver];
- North Carolina 1135 waiver request(3/17);
- North Dakota 1135 waiver request (3/18);
- New Hampshire 1135 <u>waiver</u> request (3/18); and
- South Dakota 1135 <u>waiver</u> request (3/19).
- On Sunday, CMS <u>announced</u> (3/22/20) 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.
- CMS <u>announced</u> (3/19/20) that the implementation of the Minimum Data Set 3.0 v1.181 for <u>nursing home and swing bed providers</u> set for October 1, 2020 was now delayed.
- To clarify COVID-19 coverage for the diagnosis and treatment, CMS released FAQs
 (3/18/20) 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 (3/11/20) which provides flexibility to high deductible plans to provide COVID-19 health benefits without applying a deductible or cost-sharing.
- New telehealth guidance (3/17/20) 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 (3/17/20)
 - o HHS 1135 HIPAA waiver factsheet
 - HHS Notice of Enforcement Discretion <u>factsheet</u>
 - o HHS Office of Civil Rights bulletin
 - Guidance on Business Associate Agreements
 - HIPAA Security Rule safeguards
- CMS announced steps to improve testing of patients in emergency departments with a memorandum (3/16/20) for Medicare participating hospitals, and the agency released a factsheet (3/9/20) on telehealth benefits for Medicare beneficiaries. CMS also released a memorandum (3/9/20) regarding EMTALA, allowing for alternative testing sites and other guidance.
- CMS released <u>recommendations</u> (3/15/20) last week on adult <u>elective surgeries</u> and nonessential procedures. Details include decisions are made at the local level by the clinician, patient, hospital, and state and local health departments.
- CMS <u>announced</u> 3/23/20) it will limit its **nursing home inspection** protocol to focus more specifically on complaint and infection control inspections.
 - CMS released new guidance (3/13/20) on nursing home patients and visitors.
- Last week, CMS released <u>guidance</u> 3/17/20) to Program of All-Inclusive Care for the Elderly (PACE) Organizations.
- o Information and <u>FAQs</u> (3/13/20) for individuals, issuers, and states on COVID-19 health coverage benefits.
- <u>Guidance</u> (3/10/20) 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.
- Guidance (3/10/20) regarding health care workers in home health agencies and dialysis centers.
- CMS issued <u>guidance</u> (3/10/20) to help Medicare Advantage and Medicare Part D plans respond to COVID-19.

HHS/Food and Drug Administration (FDA)

- FDA provides a daily roundup on COVID-19 related actions: March 26 actions.
- FDA issues fraud <u>alert</u> (3/25/20) on unproven and illegally marketed products that make claims, such as being effective against the coronavirus.

- FDA has continued to work with diagnostic test developers, many of which intend to submit
 applications to make tests that detect the virus. To date, 16 emergency use authorizations have
 been issued for nation-wide use. The emergency use authorization (EUA) pathway continues to
 be used.
 - For a deeper dive on FDA accelerated approval process for COVID-19 tests, see this advisory (3/23/20).
 - 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 the Pre-IND Consultation</u> <u>program</u>.
 - The FDA <u>announced</u> on March 22 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.
- On March 25, FDA issued its updated <u>enforcement policy</u> for <u>personal protective equipment</u> (PPE), exempting a broad array of face masks from FDA requirements, intended for medical personnel or the general public, where no liquid barrier protection is intended.
 - An A&B analysis of the agency's FAQs regarding the growing shortages of personal protective equipment is available here.
- FDA has announced a temporary policy to not enforce Foreign Supplier Verification Program (FSVP) onsite audit requirements under specific circumstances, and **both FDA and USDA** have also been issuing guidance to industry that addresses **food safety concerns**. Further, DHS has included the food and agriculture sector as "essential critical infrastructure," and its guidance has been used by states as they identify essential workers and businesses. A full analysis of these issues is available here. (3/25/20)
- FDA has taken actions to increase the availability of ventilators and accessories, as well as other **respiratory devices**, to support patients with respiratory failure or difficult breathing through the issuance of this March 22 enforcement policy.
- FDA has provided <u>strategies</u> to assist in the conservation of masks and gowns, as well as glove conservation <u>strategies</u>.
- FDA issued an immediately in effect <u>guidance</u> (3/20/20) 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.
- For the time being, FDA has postponed most foreign and 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 domestic inspections (3/20/20) and foreign inspections (3/12/20).
- On March 18, the FDA <u>issued</u>, "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.

HHS/Health Resources and Services Administration (HRSA)

HRSA <u>awards</u> (3/24/20) \$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>.

- This information collection effort was initiated pursuant to today's <u>waiver</u> (3/25/20) of the Paperwork Reduction Act.
- The Occupational Safety and Health Administration (OSHA) is providing this temporary guidance (3/14/20) 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 advisory (3/24/20).

Other News

- The World Health Organization (WHO) provides daily "situation" reports.
- The Joint Commission on Accreditation for Healthcare Organizations (The Joint Commission)
 <u>announced</u> (3/17/20) it was suspending surveying in response to the coronavirus outbreak. The
 suspension is expected to last through April. For additional information visit the joint
 Commission Coronavirus <u>website</u>.

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 (here)
- Facebook (here)

Centers for Disease Control and Prevention:

- Twitter (here)
- Facebook (here)

What you should know:

- Workplace, School, and Home Guidance
- People at Risk for Serious Illness from COVID-19
- How COVID-19 Spreads
- Symptoms
- Steps to Prevent Illness

- Testing
- Frequently Asked Questions
- What to Do If You Are Sick with COVID-19
- Stigma Related to COVID-19
- What You Need to Know
- Facts about COVID-19
- Information for People at Higher Risk and Special Populations
- Communication Resources

Situation Updates:

- <u>Situation Summary</u>
- Cases in the U.S.
- Global Locations with COVID-19
- Risk Assessment
- 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: COVID-19 Resources
- 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: Risk Management for COVID-19
- EPA: Disinfectants for Use Against COVID-19
- Federal Reserve: Coronavirus Disease 2019 (COVID-19) Resources.
- FDIC: Coronavirus (COVID-19) Information for Bankers and Consumers.
- OCC: COVID-19 (Coronavirus).
- Conference of State Bank Supervisors: Information on COVID-19 Coronavirus.
- NYDFS: Coronavirus: Information for Industry and Regulated Entities.
- NMLS: State Agency Communication/Guidance on Coronavirus/COVID-19

Information for Travel and Transportation:

- Information for Travel
- Guidance for Ships
- Guidance for Airlines and Airline Crew
- State: Travel Advisories
- State: Traveler's Checklist
- 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
- Resources for Healthcare Facilities
- <u>Infection Prevention and Control Recommendations for Patients with COVID-19 or Persons</u> <u>Under Investigation in Healthcare Settings</u>
- Information for Laboratories
- Resources for First Responders
- <u>Guidance for Public Health Professionals Managing People with COVID-19 in Home Care and</u> Isolation Who Have Pets or Other Animals
- FAQs and Considerations for Patient Triage, Placement and Hospital Discharge
- What Law Enforcement Personnel Need to Know
- Guidance for Homeless Shelters
- Guidance for Hemodialysis Facilities
- CMS: Information on COVID-19 and Current Emergencies
- CMS: Guidance for Hospice Agencies
- CMS: Emergency Medical Treatment and Labor Act Requirements and Implications Related 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
- Resources for Institutes of Higher Education
- Environmental Cleaning and Disinfection Recommendations Community Facilities
- USDA: USDA Makes It Easier, Safer to Feed Children in California Amid Coronavirus Outbreak
- DOE: Resources for Schools and School Personnel

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: Department of Defense Coronavirus Response

Alston & Bird Coronavirus Links

- Alston & Bird Coronavirus <u>Task Force</u> Web page
- To <u>Subscribe</u> to Alston & Bird Advisories
- For Alston & Bird COVID-19 Insights and Events
- 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>
 Coronavirus Concerns
 - o **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 Coronavirus?</u>