Coronavirus Flash Update: Monday, March 30, 2020

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The Latest News

- U.S. COVID-19 cases exceed 141,995 and 2,300 U.S. deaths. (Source: CDC)
- U.S. **stock market**: On Friday the markets gave back part of the overall rebound made earlier in the week, with the Dow falling over 900 points and S&P 500 down almost 90 points for the day, but each ending the week up over 13% and 10%, respectively, and the Nasdaq down almost 300 points for the day but ending the week up almost 10%. Weekend trading in stock futures were down between 1.5% and 1.8% as of Sunday night.
- President Donald Trump **invoked the Defense Production Act** on Friday to compel General Motors, Co. to manufacturer ventilators.
- On Sunday evening President Trump addressed the question of whether to extend the time frame for social distancing by tweeting that the "modeling estimates that the peak in death rate is likely to hit in 2 weeks...Therefore, we will be extending our guidelines to April 30, to slow the spread."

COVID-19 Related Legislation

• On Friday afternoon, the U.S. House of Representatives passed the **Coronavirus Aid, Relief, and Economic Security (CARES) Act,** H.R. 748, by voice vote. Within hours President Trump took prompt action when he signed the bill into law. The Senate had given its approval to the CARES

Act on Wednesday night by a vote of 96-0. The CARES Act is the third bill in 3 weeks in response to the pandemic, lending the bills shorthand names of 1.0, 2.0, and now 3.0 for the CARES Act. The \$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.

- The bill text is available <u>here</u> and a section by section summary is available <u>here</u>. A&B has summarized most sections of the bill:
 - A&B Summary CARES Act Health Provisions
 - O A&B Overview CARES Act Health Care Grants and Reimbursement Changes
 - A&B Overview CARES Act Key Health Care Appropriations
 - O A&B Overview CARES Act Funding Sources:
 - \$367 billion for Small Business Administration
 - o \$500 billion for the Treasury's Business Stabilization Loan Fund
 - o Tax Credits and Other Potentially Beneficial Tax Considerations
 - A&B Summary CARES Act Small Business Provisions
 - A&B Summary CARES Act Educational Provisions and Appropriations
- The federal agencies will be rapidly developing and releasing guidance for the funding and other provisions the bill requires. As an example, one day after the bill's enactment the Centers for Medicare and Medicaid Services released guidance on the accelerated and advance payment program, as required by the CARES Act. The announcement included a statement and fact sheet.
 - o For addition analysis, read this A&B advisory (3/30/20) on the CMS guidance.
- On a House Democratic Conference call last week, House Majority Leader Steny
 Hoyer (D-MD) told his colleagues there will likely be a "fourth" and "fifth" phase of
 pandemic relief. 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 passed two other coronavirus response bills during the past 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) (<u>H.R. 6201</u>), 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

• 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 blog (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 Commerce

- Small Business Administration (SBA)
 - o In response to the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) requirements, the SBA just released <u>guidance</u> (3/30/20) on how to make a loan under SBA's Economic Injury Disaster Loan Program to the qualified entities listed in this application that are impacted by the Coronavirus (COVID-19).
 - A&B advice: borrowers and lenders are reminded of the care they should take that all information used to secure funding under the new law is accurate and true in all material respects. As with traditional SBA loans, those that resulted from the American Recovery and Reinvestment Act, and other government financial programs, we can expect future government investigations by the Office of the Special Inspector General for Pandemic Recovery (established by the CARES Act), the SBA Office of Inspector General, and other Inspector Generals, and claims under the False Claims Act if, for example, false information with respect to a company's size or payroll, is provided in order to secure a loan or increase loan forgiveness under the law.
- 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.
 - 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 legislation 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.

Department of Health and Human Services

- On March 25, pursuant to the President's <u>Executive Order</u>, the <u>Department of Health and Human Services (HHS)</u> 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.

Assistant Secretary for Preparedness and Response

- 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.

Centers for Disease Control and Prevention

- 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.

Centers for Medicare & Medicaid Services

- **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 <u>here</u>.
- In response to the **Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**, CMS has released the first guidance required under the Act:
 - The Act required CMS to expand its accelerated and advance payment program, and on March 28 a <u>statement</u> and <u>fact sheet</u> were released providing guidance on the policy.
 - For additional analysis, read this A&B advisory (3/30/20) on the CMS guidance.
- CMS, on behalf of Vice President Mike Pence, sent a <u>letter</u> to the nation's hospitals requesting they report data in connection with their efforts to fight the COVID-19 pandemic. Among the details requested are daily reports regarding bed capacity and supplies.
- 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:
 - 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: <u>guidance</u>).
 - 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 guidance (3/13/20).
- On March 24, CMS posted notice that it had <u>withdrawn</u> its proposed **rule to tighten Medicaid eligibility** determination.
- 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 <u>FAQs</u> (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 template.
 - 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 34 states for coronavirus 1135 waivers, and for more details and the full list CMS approved 1135 waivers can be found here.
 - 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 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 (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:
 - CMS issued an electronic <u>toolkit</u> regarding telehealth and telemedicine for Long Term Care Nursing Home Facilities (3/28/20)
 - CMS telehealth FAQs (3/17/20)
 - HHS 1135 HIPAA waiver factsheet
 - HHS Notice of Enforcement Discretion factsheet
 - 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.
- The Occupational Safety and Health Administration (OSHA) is providing this temporary guidance (3/14/20) regarding required annual N-95 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> (3/24/20).
- <u>CMS 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.
- CMS Guidance (3/10/20) regarding health care workers in home health agencies and dialysis centers.

Food and Drug Administration

- FDA provides a daily roundup on COVID-19 related actions: March 27 actions.
- FDA has issued an <u>enforcement policy</u> to increase the availability and capability of **sterilizers**, disinfectant devices, and air purifiers in health care settings.
- 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. DHS has included the food and agriculture sector as "essential critical infrastructure," and a full analysis of these issues is available here.
- Both <u>USDA FSIS</u> and <u>FDA</u> have issued enforcement discretion policies to provide labeling flexibilities for products intended for **food service going to retail**.
- To date, FDA has issued 16 <u>emergency use authorizations</u> for FDA-regulated devices in health care settings. For deeper dive on FDA accelerated approval process for COVID-19 tests, see this <u>advisory (3/23/20)</u>.
- 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 enforcement policy.
- Last week, FDA issued its <u>enforcement policy</u> for **face masks** and surgical masks, exempting a broad array of face masks from FDA requirements, 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 <u>here</u>.
- FDA has provided <u>strategies</u> to assist in the conservation of masks and gowns, as well as glove conservation <u>strategies</u>.
- 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 <u>domestic inspections</u> (3/20/20) and <u>foreign inspections</u> (3/12/20).
- FDA previously <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.

Health Resources and Services Administration

- HRSA released <u>guidance</u> (3/27/20) noting the COVID-19 public health emergency warranted additional flexibilities regarding **340B covered entities**, including allowing self-reporting of patient identity, condition, and history for purposes of 340B recordkeeping requirements.
- 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>.
- HRSA released <u>waiver</u> (3/25/20) of the Paperwork Reduction Act.

Department of Homeland Security/Department of Defense

- The **Department of Homeland Security (DHS)** <u>announced</u> (3/26/20) that the deadline to enforce REAL ID requirements would be delayed 12 months to October 1, 2021.
- The **Cybersecurity and Infrastructure Agency (CISA)** released updated <u>guidance</u> (3/28/20) on critical infrastructure workers.
- Federal Emergency Management Agency (FEMA) has established How to Help website for individuals and organizations interested in helping the effort to combat the spread of COVID-19. Examples of assistance offered include:
 - To **sell medical supplies** or equipment to the federal government, please email specifics to covidsupplies@fema.dhs.gov.
 - If you have **medical supplies or equipment to donate**, please <u>provide us details</u> on what you are offering.
 - If you are a private company that wants to **produce a product related** to the COVID-19 response email nbeoc@max.gov.
 - For **non-medical** supplies, services or equipment, if you are interested in doing business with FEMA, visit <u>Industry Liaison Program</u>.
- FEMA provides <u>guidance</u> (updated regularly) 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 **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 Justice/Federal Trade Commission

- On March 23, President Donald Trump released an <u>Executive Order</u> on hoarding and <u>price</u> 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 <u>advisory</u> (3/26/20).
- On March 27, the FTC sent <u>letters to nine VoIP providers</u> and other companies warning them that "assisting and facilitating" illegal telemarketing or robocalls related to the Coronavirus pandemic, including by providing VoIP services, is against the law. The warning letters note that combatting illegal robocalls, especially those involving Coronavirus, are a top priority for the FTC. This is the second time the FTC sent warning letters to companies for their actions related to the pandemic. Earlier in the month the FTC and FDA sent <u>warning letters</u> to seven companies about unsupported claims that products can treat or prevent Coronavirus.
- The FTC Chairman Joe Simons issued a <u>statement</u> (3/26/20) 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: <u>business.covid@ftc.gov</u>, 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.
- 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.
 - 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 <u>advisory</u>. (3/19/20)
 - Federal antitrust agencies to extend merger reviews. 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 <u>notice</u> (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. The agencies began receiving federal premerger notification (Hart-Scott-Rodino Act) filings exclusively via electronic submission and <u>announced</u> (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)

Department of Labor

- Department of Labor (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 as required by the Families First Coronavirus Response Act The posted page 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 guidance (3/24/20) with fact sheets for employers and employees.
 - DOL issued updated <u>FAQs</u> on the paid sick and family leave requirements that **define** "health care providers" and "emergency responders" that employers may exempt from
 the leave requirements.
 - In general, new Q&A 56 defines a "health care provider" to include "anyone employed at any doctor's office, hospital, health care center, clinic, post-secondary educational institution offering health care instruction, medical school, local health department or agency, nursing facility, retirement facility, nursing home, home health care provider, any facility that performs laboratory or medical testing, pharmacy, or any similar institution, employer, or entity. This includes any permanent or temporary institution, facility, location, or site where medical services are provided that are similar to such institutions."
 - In general, Q&A 57 defines an "emergency responder" as "an employee who
 is necessary for the provision of transport, care, health care, comfort, and
 nutrition of such patients, or whose services are otherwise needed to limit the
 spread of COVID-19." This also includes "individuals who work for such
 facilities employing these individuals and whose work is necessary to maintain
 the operation of the facility." See the FAQs for additional detail.

- 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
 - OSHA's COVID-19 website (3/20/20)
 - 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)
 - o Employee Leave Requirements Under FFCRA advisory (3/19/20)
 - o COVID-19 FAQs (3/19/20) for Employers
- DOL/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.

Department of 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.
- Government required stay-at-home orders have forced people to give significant focus on the use of electronic signatures and the maintenance of electronic records. This A&B <u>advisory</u> (3/27/20) reviews the three main laws that govern electronic signatures.
- 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.
 - o 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.
- 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:
 - o Coronavirus <u>Tax Relief</u>. (3/13/20)
 - o IRS Operations During COVID-19: Functions continue guidance. (3/24/20)
 - Filing and payment deadlines FAQs. (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)

Securities and Exchange Commission

- The Securities and Exchange Commission (SEC) issued an amended order (3/25/20) extending
 the relief available to some companies that cannot timely file their reports due to concerns,
 including the need to update risk disclosures in response to business threats. Additional detail is
 provided in this A&B advisory (3/27/20).
- The SEC issued **Disclosure Guidance** <u>Topic No. 9</u> (3/25/20) on the SEC's current views regarding disclosure and other securities law obligations that companies should consider with respect to COVID-19 and related business and market disruptions.
- The SEC also issued a <u>statement</u> (3/24/20) regarding the authentication document retention requirements under the SEC rules in light of health, transportation and other logistical issues raised by the spread of COVID-19.
- Companies will need to vigilantly monitor insider trading despite the SEC's statements on relaxed disclosure and other regulations. These issues are examined in this A&B <u>advisory</u> (3/26/20).

Other Agencies

- Environmental Protection Agency (EPA) issued an enforcement memo, "<u>COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program</u>" (3/26/20), 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 hoursof-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).
- The Department of Agriculture Rural Development Division has launched a <u>resource page</u> to help rural residents, farmers, and businesses stay current on the Agency actions related to COVID-1(
- The **construction industry** is confronting multiple coronavirus related crises. To understand the trends read this A&B advisory (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).

Trade and International Business Issues

- 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 physical 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 <u>advisory</u>. (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.

Additional Workplace 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>Kansas</u>, <u>Kentucky</u>, <u>Louisiana</u>, <u>Massachusetts</u>, <u>Michigan</u>, <u>Minnesota</u>, <u>Montana</u>, <u>Newada</u>, <u>New Hampshire</u>, <u>New Jersey</u>, <u>New Mexico</u>, <u>New York</u>, <u>North Carolina</u>, <u>Ohio</u>, <u>Oregon</u>, <u>Pennsylvania</u>, Washington, West Virginia, Wisconsin, and Vermont.

- For those asking how to define "federal crucial infrastructure sectors" the Department of Homeland Security's Cyber Infrastructures division <u>outlines</u> (last update 3/28/20) 16 sectors and provides additional guidance for businesses.
 - 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 advisory (3/18/20).
- o The Council of State Governments provides a <u>website</u> linking to all state orders.

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.
- 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).

Other News

- The World Health Organization (WHO) provides daily "situation" reports.
- The Joint Commission on Accreditation for Healthcare Organizations (The Joint Commission) announced (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 website.

For background and the most up-to-date information, please visit the Centers for Disease Control and Prevention Coronavirus Disease 2019 website: HERE. 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:

- Situation Summary
- 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
- FEMA: Coronavirus Response
- 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 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 Task Force Web page
- To Subscribe to Alston & Bird Advisories
- For Alston & Bird COVID-19 Insights and Events
- Previous Alston & Bird Coronavirus Advisories (not included in the above)

o March 16

- Securities Law Advisory: SEC Provides Guidance on the Possible Impacts of COVID-19 on Annual Meetings
- Health Care / Cybersecurity Preparedness & Response Advisory: COVID-19 and HIPAA: Privacy, Security, and Breach Response During a Global Pandemic

o March 13

- <u>Financial Services & Products Advisory: FINRA Guidance: COVID-19 and Business</u>
 Continuity Planning
- Food, Drug & Device/FDA Advisory: FDA Seeks Help to Solve Personal Protective Equipment Shortages
- Securities Litigation Advisory: Securities Litigation Risk Arising Out of the Coronavirus Pandemic

March 12

■ FDA Compliance & Enforcement Advisory: FDA Postpones Foreign Inspections
Through April 2020: Considerations for Industry

o March 10

<u>Labor & Employment / Health Care Advisory: Coronavirus, Employers, and</u>
 Domestic Travel: A Complicated Business Decision

March 6

 Securities Law Advisory: SEC Provides Conditional Relief to Companies Affected by COVID-19

o March 5

Health Care Advisory: Congress Expands Medicare Telehealth Benefit Amid
 Coronavirus Concerns

February 28

<u>Labor & Employment / Health Care Advisory: The Coronavirus: Employer and Workplace Considerations</u>