Coronavirus Flash Update: Wednesday, April 8, 2020

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The Latest News

- U.S. COVID-19 cases exceed 397,754 and 12,956 U.S. deaths. (Source: CDC)
- U.S. **stock market**: Tuesday ended with the U.S. benchmarks down slightly from Monday's gains, with the Dow losing 26 points, the S&P down 4 points, and the Nasdaq dropping 25 points.
- Late Tuesday, Centers for Medicare and Medicaid Services Administrator Seema Verma announced that of the \$100 billion from the CARES Act health care providers Public Health and Social Services Emergency Fund (PHSSEF), \$30 billion will go directly to providers based on Medicare revenue as grants to be dispersed within the next week with "no strings." The grants will be based on Medicare revenue. Administrator Verma acknowledged that non-Medicare providers (e.g., children's hospitals, pediatricians, OB/GYN, some nursing homes) will not have access to the initial \$30 billion distribution and will be addressed in the next wave of disbursements. An additional \$64 billion will go to providers with certain criteria not yet

detailed. A full transcript of Administrator Verma's remarks, as well as remarks by President Trump and others, at Tuesday's White House Press Briefing can be found here.

- HHS Secretary Alex Azar stated last week that a portion of the \$100 billion PHSSEF health care provider assistance would be payments linked to the COVID-19 care for the uninsured.
- The Paycheck Protection Program (PPP) may receive an additional \$250 billion in funding later this week. On Tuesday, Senate Majority Leader Mitch McConnell (R-KY) released a statement that it was his intent to seek additional funding for the small business loan program and to do so by unanimous consent or voice vote on Thursday. He stated that the "small-business Paycheck Protection Program needs more funding...is quickly becoming clear that Congress will need to provide more...nearly 10 million Americans filed for unemployment in just the last two weeks. This is already a record-shattering tragedy and every day counts."
 - By Tuesday morning, the Small Business Administration had processed \$70 billion in emergency loans, well on its way through the \$350 billion which the CARES Act authorized.
 - This emergency PPP funding legislation is already being tagged 3.5 since it will be limited to just additional dollars for an under-funded program authorized in the CARES Act. Work on a larger, more comprehensive bill, 4.0, will remain underway.
- The White House unveiled a new hashtag, #AmericaWorksTogether, that will be used to promote companies that are hiring employees during the economic crisis and donating food and other supplies to health care workers.

COVID-19 Related Legislation

- **Bill 4.0**: Despite the side bar action this week to seek quick approval for an additional \$200-250 billion in funds for the Paycheck Protection Program as a part of bill "3.5," Congress continues work to develop a larger 4.0 bill. Democrats hope to move the next bill before the end of April and their priorities include expanded health care coverage and hazard pay for health care and other essential workers. Congressional Republicans prefer to wait until May to gauge more fully the nation's needs, and their priorities may include infrastructure spending.
- Bill 3.0: Coronavirus Aid, Relief, and Economic Security (CARES) Act, (H.R. 748) passed on March 27. The CARES Act is a \$2.2 trillion-dollar package and includes \$500 billion in financial assistance for distressed businesses, \$349 billion in low-interest small business loans, and \$100 billion in financial assistance for Medicare/Medicaid enrolled health care providers and suppliers. The bill also includes \$1,200 in financial assistance for the lowest income taxpayers, an additional 13 weeks of unemployment compensation benefits, and an employee extension credit.
 - A congressional section by section summary is available here.
 - A&B detailed summaries are below:
 - A&B Summary CARES Act Health Provisions
 - A&B Overview CARES Act Health Care Grants and Reimbursement Changes
 - A&B Overview CARES Act Key Health Care Appropriations
 - A&B Analysis CARES Act Funding Sources (Updated 4/8/20):

- \$367 billion for Small Business Administration
- Paycheck Protection Loan program (updated per the Interim Final Rule)
- \$500 billion for the Treasury's Business Stabilization Loan Fund
- Tax Credits and Other Potentially Beneficial Tax Considerations
- A&B Summary CARES Act Small Business Provisions
- A&B <u>Summary</u> CARES Act Educational Provisions and Appropriations
- A&B Summary CARES Act Individual and Business Tax Provisions
- A&B <u>Summary</u> **CARES Act Unemployment Provisions**
- A&B Summary CARES Act Labor Provisions
- A&B <u>Guide</u> -- how the CARES Act refundable Employer Retention tax credit for employers works
- A&B <u>Hospital Provisions Tracking Document</u> of COVID-19 Provisions Impacting Hospitals from all three bills (Updated on 4/8/20))
- A&B Summary of oversight and enforcement provisions in the CARES Act (New)
- Congress has passed three coronavirus emergency response bills and the first two are below:
 - Bill 1.0: Coronavirus Preparedness and Response Supplemental (CPPRS) (<u>H.R. 6074</u>)
 passed on March 5.
 - Bill 2.0: Families First Coronavirus Response Act (FFCRA) (<u>H.R. 6201</u>) passed on March 18.

Key Administrative and Regulatory Actions

- For the **third time** in a week (4/2/20), **President Trump has** <u>invoked</u> the <u>Defense Production Act</u> and ordered a ban on exports by 3M Co. of scarce supplies, including N95 respirators, surgical masks, and gloves.
 - Earlier last week, the President <u>ordered</u> the Secretaries of the Departments of Health and Human Services and Homeland Security to "help domestic manufactures like General Electric, Hill-Rom, Medtronic, ResMed, Royal Philips, and Vyaire Medical secure the supplies they need to build ventilators needed to defeat the virus."
- 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

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.

Department of Defense

- The Office of the Under Secretary of Defense released a memo (4/2/20) stating that DoD contracts contain clauses that provide "that a contractor will not be in default because of a failure to perform the contract if the failure arises beyond the control and without the fault or negligence of the contractor."
- The President announced an <u>executive order</u> (3/30/20) to <u>order up to 1 million Ready Reserve</u> members to active duty for up to two years at a time to assist the nation in this national emergency. He authorized 100% federal cost-sharing for the governors of Connecticut, Illinois, Michigan, Florida, Louisiana, Maryland, Massachusetts, New Jersey, Guam, and Puerto Rico to use National Guard to support state and local emergency assistance for 30 days.
- The Army Corps of Engineers released a <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. More information regarding contracting with the Army Corps of Engineers is available <u>here</u>. (Updated 4/7/20)

Environmental Protection Agency

- On April 3, Environmental Protection Agency (EPA) Administrator Wheeler <u>outlined steps</u> to protect against fraudulent disinfectant claims.
- The EPA <u>identified</u> (4/7/20) approximately 225,000 pieces of personal protection equipment they will donate to state and local responders. (New)
- On April 2, the EPA revised <u>List N: Disinfectants for Use Against SARS-CoV-2</u> to include products on EPA's List G: Products effective against norovirus, and List L: Products effecting against the Ebola virus, as EPA has determined that these products also meet its criteria for use against SARS-CoV-2. There are now 357 disinfectants on List N. EPA has updated the list to include the specific types of surfaces products can be used on, such as hard or soft surfaces; use sites, such as hospital, institutional or residential; and whether a product can be applied by fogging.
 - The EPA will temporarily <u>allow</u> (3/31/20) manufacturers of already-registered EPA disinfectants on EPA's List N: Disinfectants for Use Against SARS-CoV-2 to obtain certain active ingredients from any supplier without checking with the agency for approval.
- EPA issued an enforcement memo, "COVID-19 Implications for EPA's Enforcement and
 Compliance Assurance Program" (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.
- 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."

Federal Communications Commission

- The Federal Communications Commission (FCC) issued (4/3/20) an order waiving the content sponsorship requirements during commercial advertising time. The purpose of the order is to permit companies that have purchased advertising time to donate the time for the purpose of broadcast public service announcements prepared by the CDC or other governmental or public health agencies regarding COVID-19 (New).
- The FCC <u>provided relief</u> on April 1 to enable rural broadband and phone providers to immediately waive consumer fees, including late payment and installation and cancellation fees, in order to help Americans work from home or access remote learning.
 - The FCC adopted a <u>program</u> for \$200 million in COVID-19 telehealth grants (the COVID-19 Telehealth Program) and \$100 million in grants through the Connected Care Pilot Program to assist hospitals, and other health care providers cover telehealth costs. The funds for both were authorized by the **CARES Act**.
 - The FCC is now accepting applications for <u>COVID-19 Telehealth Program</u>. The Wireline Competition Bureau will review applications, select participants, make funding awards on a rolling basis, and will announce such information.
 - To apply, applications must be submitted through the FCC's <u>Electronic Comment Filing System</u> (ECFS), inputting "20-89" in the "Proceeding(s)" box and completing the form, including the required information described in the <u>Report and Order</u>. Applicants also must send a courtesy copy of the application via email to <u>EmergencyTelehealthSupport@fcc.gov</u>.
 - Applicants can obtain an <u>eligibility determination</u> by filing an FCC <u>Form 460</u> with the Universal Service Administrative Company (USAC). <u>Applicants can still submit</u> an application for the COVID-19 Telehealth Program while the Form 460 application is pending.
 - The FCC also provided additional details on the <u>Connected Care Pilot Program</u>. The selected pilot projects will be supported for a three-year funding period, with separate transition periods of up to six months before and after the funding period (up to four years total).

- Applicants must first obtain a USAC eligibility determination (Form 460, noted above). After confirming eligibility, the applicant must submit its pilot project proposal to the FCC.
- The FCC plans to provide an application form ("Connected Care Pilot Program Application") that must be used when submitting project proposals to the FCC. Submitted applications must reference WC Docket No. 18-213. Applicants may file using the ECFS, but also must send a courtesy copy of the application via email to ConnCarePltProg@fcc.gov.
 - The deadline for filing applications will be 45 days from the effective date of the Connected Care Pilot Program rules or 120 days from the release date of the Report and Order (whichever is later).
- Additional details on the application and evaluation process, including key information on eligibility, certain required certifications, and how the FCC will choose participants, are available in the Report and Order.

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.
- HHS has unveiled a **COVID-19 Resources page**.
- The **HHS Office of Inspector General (HHS-OIG)** <u>issued</u> (4/3/20) a policy statement regarding the application of previously issued blanket waivers to **Anti-Kickback Statute** sanctions (**New**).
 - OIG announced its decision to exercise its enforcement discretion to not impose administrative sanctions under the federal Anti-Kickback Statute (AKS) for certain renumeration related to COVID-19. Specifically, OIG is applying 11 of the 18 waivers previously issued by CMS for physician self-referral law sanctions to administrative sanctions imposed under:
 - Section 1128(b)(7) of the Social Security Act (permitting the HHS Secretary to exclude parties committing fraud or offering kickbacks from participating in a federal health care program); and
 - Section 1128A(a)(7) of the Social Security Act (also known as the AKS, which
 criminalizes the knowing and willful payment of "remuneration" to induce or
 reward patient referrals for any item/service payable by a federal health care
 program).
 - OIG Policy Statement Applies Only to the Following Blanket Waivers
 - Waiver for personally performed services
 - Waivers for certain rental rates
 - Waivers for purchase of items and services
 - Waivers for certain physician compensation arrangements
 - See our previously published A&B <u>Health Care Advisory</u> analyzing each category of waivers.

- o Applicability and Takeaways of Blanket Waivers for AKS Sanctions
 - All of the conditions and definitions that apply to the blanket waivers shall apply to the Policy Statement regarding AKS sanctions.
 - This Policy Statement shall apply to conduct occurring on or after April 3, 2020.
 - The OIG Policy Statement regarding AKS sanctions expires the same date the CMS blanket waivers expire.
 - The OIG Policy Statement can't be relied upon for conduct that takes place after the blanket waivers expire.
 - The OIG Policy Statement does not apply to arrangements that implicate the AKS that are <u>not</u> covered by the blanket waivers. It is currently unclear whether blanket waivers for AKS sanctions are retroactive to March 1, 2020.
- HHS <u>announced</u> on Tuesday it is <u>purchasing the ID NOW COVID-19 rapid point-of-care test</u> for state, territorial and tribal public health lab use (New).
- The HHS Office of Civil Rights <u>announced</u> (4/2/20) that it will exercise its <u>enforcement discretion</u> and will not impose penalties for violations of certain provisions of the <u>HIPAA Privacy Rule</u> against health care providers or their business associates for the good faith uses and disclosures of protected health information (PHI) by business associates for the public health and health oversight activities during the COVID-19 nationwide public health emergency. This <u>notice</u> is effective immediately.
- 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 in March.

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.
- ASPR has created several resource sites for peers to share COVID-19 best practices on promising
 practices, plans, tools, or templates on <u>supply chain</u>, <u>fatality management</u>, and <u>emergency</u>
 <u>departments</u> (New).

Centers for Disease Control and Prevention

- For the most up to date **CDC guidance** visit <u>here</u>. The CDC has also added a series of **Training for Health Professionals webinars** (**New**).
- The CDC <u>issued</u> (4/7/20) guidance for businesses and buildings on how to ensure that water systems are safe to use after prolonged shutdowns (New).
- The CDC <u>updated</u> (4/7/20) its personal protection equipment (PPE) **burn rate calculator** to help health care providers plan and optimize the use of PPE response to COVID-19 (New).
- The CDC has released a <u>report</u> (4/7/20) on **COVID-19 illness in children** which includes topline findings on diagnosing and treating children with COVID-19 (New).
- HHS <u>announced</u> (4/6/20) that the **CDC** would provide **\$186** million in funding to state and local jurisdictions to respond to COVID-19 (New).

- For pharmacy staff, the CDC has posted <u>information</u> on strategies to minimize risk of exposure.
 (New)
- The Centers for Disease Control and Prevention <u>announced</u> on Friday its recommendation that **everyone use a simple cloth over one's face** to slow the spread of the virus. The cloth does not need to be a face mask (or N95) and can be fashioned from household items.
- The CDC updated its <u>recommendations</u> (4/3/20) on **optimizing the supply of PPE**.
 - The CDC also released <u>guidance</u> on the collection and submission of postmortem specimens from deceased person with COVID-19, and last week multiple new areas of <u>information</u> was posted on: health care providers and pregnant women; pediatric providers and children; what law enforcement need to know; what school administrators need to know; and PPE for individuals caring for a COVID-19 patients.
- On March 25, the CDC published two preparedness checklists: one for <u>health care professionals</u> and one for <u>hospitals</u>.
- 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 persons who live in nursing facilities, are 65 or older, have underlying medical conditions, or are first responders.
 - The CDC also updated its infection control guidance.
 - The CDC's FAQs (3/22/20) for health professionals.

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>. The number of CMS conference call updates and webinars keep a steady pace:
 - o CMS held a COVID-19 Update call on Tuesday and provided a slide <u>presentation</u> (New).
 - o "Office Hours" was the first in a series of calls with providers to ask questions on
 - A special telehealth Open Door Forum call is scheduled for Wednesday, April 8 at 1:30 pm EST (1-888-455-1397, Participant code: 3535324) (New).
 - CMS released a <u>video</u> on the common questions regarding Medicare's **telehealth** services benefit (New).
 - Also, on Wednesday, CMS is hosting a call on nursing home COVID-19 care at 4:00pm
 EST (1-833-614-0820, Conference ID 6798274 weblink is available here (New).
- CMS <u>issued</u> (4/7/20) a dear clinician letter that outlines a summary of actions CMS has taken to
 ensure clinicians have maximum flexibility to reduce unnecessary barriers to providing patient
 care during the unprecedented outbreak of COVID-19. The summary includes information about
 telehealth and virtual visits, accelerated and advanced payments, and recent waiver
 information (New).
- The Agency <u>announced</u> on Tuesday it had <u>approved</u> approximately \$34 Billion for providers in accelerated or advance payments. Of the 25,000 requests received, CMS had approved 17,000 during the program's first week (New).
- A new COVID-19 ICD-10 diagnosis code was announced by CMS and is effective April 1 (New).

- CMS <u>updated</u> (4/7/20) its recommendations to postpone non-essential surgeries and other procedures to conserve critical health care resources and limit exposure of patients and staff to COVID-19 (New).
- CMS <u>issued</u> on Tuesday (4/6/20) a **Medicare Advantage and Part D** rate announcement for CY 2021 with an 1.66% average change in revenue relative to last year. The announcement does not catalog CMS's actions regarding COVID-19, but these are <u>explained</u> in a summary included with the announcement (New).
- Late Thursday (4/2/20), CMS <u>issued</u> recommendations to **nursing homes** and state and local governments on infection control in long term care. The <u>recommendations</u> include:
 - Nursing homes should immediately ensure that they are complying with all CMS and CDC guidance related to infection control.
 - CMS/CDC urges State and local leaders to consider the needs of long-term care facilities with respect to supplies of PPE and COVID-19 tests.
 - Nursing homes should immediately implement symptom screening for all staff, residents, and visitors – including temperature checks.
 - Nursing homes should ensure staff are using appropriate PPE, to the extent PPE is available and per CDC guidance on conservation of PPE.
- CMS <u>announced</u> on Monday (3/30/20) that it will suspend audit activity, stating that, "The
 agency will continue to engage in oversight activities but will suspend requesting additional
 information from providers, healthcare facilities, Medicare Advantage and Part D prescription
 drug plans, and States."
- On March 30, CMS released an Interim Final Rule, which made numerous regulatory changes to
 provide additional flexibility for health care providers and temporarily remove certain
 limitations on care delivery. These changes have retroactive applicability to March 1. While
 many of these changes were developed prior to the enactment of the Coronavirus Aid, Relief,
 and Economic Security Act (CARES Act), significant flexibility has been conferred during the
 COVID-19 public health emergency, including:
 - Expanded use of telehealth; Removing the face-to-face or in-person requirements where required by NCDs and LCDs;
 - Changes intended to increase hospital capacity (e.g., allowing hospitals to provide services in other sites of care);
 - Additional flexibility to expand the health care workforce, including relaxing teaching physician presence requirements and providing liability protection for health care volunteers;
 - Amending the calculations for Medicare Advantage and Part D star ratings; and
 - Providing relief for participants in certain CMS demonstration programs, the Quality
 Payment Program, and the Medicare Shared Savings Program.

CMS CARES Act Guidance

- In response to the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), CMS continues to release guidance required under the Act:
 - On March 30, CMS announced sweeping changes in response to requirements of the CARES Act. The changes are summarized in this CMS <u>release</u>. The new waivers and flexibilities for health care providers are outlined by CMS in the following:

CMS new waivers and flexibilities:

- Summary of COVID-19 Emergency Declaration Waivers & Flexibilities for Health Care Providers (PDF)
- <u>List of Blanket Waivers</u> (4/3/20) (New)
- Blanket waivers of Section 1877(g) of the Social Security Act
- Medicare IFC: Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC) (PDF)
 - o <u>IFC Federal Register Announcement</u> (4/1/20) (New)
- Graphic Overview of Flexibilities (PDF)
- Provider Burden Relief Frequently Asked Questions (PDF)
- <u>Provider Enrollment Relief Frequently Asked Questions (PDF)</u>
- Updates for State Surveyors and Accrediting Organizations (EMTALA and Infection Control)
- Reprioritization of PACE, Medicare Parts C and D Program, and Risk Adjustment Data Validation (RADV) Audit Activities (HPMS Memo)
- Provider-specific fact sheets on new waivers and flexibilities are available <u>here</u>.
 - o Need a deeper dive on these new waivers?
 - The EMTALA waiver provides greater flexibility for hospitals to manage medical screening examinations (MSEs). For additional analysis, read this A&B <u>advisory</u> (4/1).
 - CMS also announced blanket waivers of sanctions imposed under the physician self-referral laws. For a detailed discussion of this issue, read this A&B advisory (4/1).
 - The telehealth expansion waiver, which was originally expanded in the Coronavirus Preparedness and Response Supplemental Act (1.0), was further expanded in the CARES Act.
 - CMS released an <u>information bulletin</u> (4/2/20) on telehealth for Medicaid substance use disorder services.
 - The full details of the latest **telehealth changes** are discussed in this A&B <u>advisory</u> (3/31/20).
 - 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 HIPAA Security Rule safeguards
 - HHS Notice of Enforcement Discretion factsheet
 - HHS Office of Civil Rights bulletin
 - Guidance on Business Associate Agreements

- The CARES 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 <u>advisory</u> (3/30/20) on the CMS guidance.
 - CMS <u>announced</u> on 4/7/20 that it had delivered nearly \$34 billion in the past week to providers in addition to the \$100 billion provided for in the CARES Act. CMS stated that it had approved 17,000 out of over 25,000 requests received in the past week (New).
- CMS, on behalf of Vice President Mike Pence, sent a <u>letter</u> (3/30/20) to the nation's hospitals requesting (not requiring) they report data, including on testing, bed capacity, and supplies connection with their efforts to fight the COVID-19 pandemic.
- 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.
- On **1135 Waivers**: Further information continues to be released on blanket waivers after the initial <u>guidance</u> (3/13/20) response to the national emergency executive order.
 - CMS issued provider enrollment FAQs for 1135 blanket waiver, available <u>here</u> (3/22/20).
 - o 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.
 - CMS has approved 49 coronavirus 1135 waivers, and for more details and the full list <u>CMS approved 1135 waivers can be found here</u>. And on March 27, CMS announced the approval of 16 state hospital associations in one letter (it can be found <u>here</u> and additional <u>information</u>.)
- The National Uniform Billing Committee has provided <u>guidance</u> on <u>claims for COVID-19</u> treatment and approved the use of DR (disaster related) condition code for services related to the coronavirus.
- 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 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: <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: <u>FAQs</u>).
 - CMS released FAQs on prescription drugs and COVID-19 for health insurance issuers in individual and small group markets (see: <u>FAQs</u>).
- 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.

Medicaid:

- o On April 2, CMS <u>updated their Medicaid FAQs</u>.
- CMS posted notice (3/24/20) 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 tools (3/20/20) for state Medicaid and Children's Health Insurance Programs (CHIP) and updated 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>.
- 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.
- 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).

Food and Drug Administration

- FDA provides a daily roundup on COVID-19 related actions (<u>latest announcement</u> (4/7/20), <u>all announcements</u>).
 - The agency published a public database of drug shortages.
- FDA <u>released</u> (4/6/20) guidance on the temporary flexibility regarding the **Egg Safety Rule** to permit producers who sell eggs to facilities for further processing to sell to the table egg market (New).
- FDA issued (4/6/20) an FAQ from members of the animal food industry on COVID-19 (New).
- FDA <u>issued</u> (4/5/20) an FAQ on **3D printing** of medical devices and other equipment during the COVID-19 pandemic (New).
- Last Friday (4/3/20), the FDA <u>announced</u> it will temporarily conduct remote importer inspections under the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP).
- FDA has provided updated <u>guidance</u> (4/2/20) to address the **need for blood donations** during the coronavirus crisis, including immediate changes to the eligibility criteria.
- FDA continues to issue <u>emergency use authorizations</u> for ventilators, PPE, diagnostic tests, and on April 1, the first COVID-19 test that looks for antibodies in the blood was authorized for treatment of COVID-19.
 - For a deeper dive on FDA accelerated approval process for COVID-19 tests, see this A&B advisory.
- FDA <u>announced</u> (3/31/20) the **Coronavirus Treatment Acceleration Program** (CTAP), a new program to expedite the development of potentially safe and effective life-saving treatments.
- On April 1, FDA released a temporarily **enforcement discretion policy** to provide flexibility to chain restaurants and similar retail food establishment subject to FDA's menu labeling



- requirements. Under its policy, FDA will not object if covered establishments do not comply with menu labeling requirements until "conclusion of the public health emergency."
- FDA has issued enforcement policies to increase the availability of <u>ventilators and accessories</u>, face masks and respirators, gowns, other apparel and gloves, sterilizers, disinfectant devices, and air purifiers, clinical electronic thermometers, infusion pumps and accessories, remote ophthalmic devices and monitoring devices, and extracorporeal membrane oxygenation and cardiopulmonary bypass devices (Updated 4/7/20).
 - The FDA updated its <u>FAQs</u> (4/2/20) on surgical masks and gown shortages.
 - An A&B analysis (3/13/20) of the agency's FAQs regarding the growing shortages of personal protective equipment is available here.
 - 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 <u>guidance</u> on notifying FDA of permanent discontinuation or interruption in manufacturing.
- The CARES Act includes OTC drug reform that would create an OTC drug user fee system, ensure FDA can approve OTC medicines without going through a full notice and comment rulemaking and allow for 18-month exclusivity for certain OTC drugs.
- In the midst of ongoing **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.
- 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.
- 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 <u>updated its FAQs</u> (4/2/20) for **health centers** with additional questions to address the Federal Tort Claims Act among other flexibilities that have been enacted.
 - 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 here.
- 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 released waiver (3/25/20) of the Paperwork Reduction Act.

Department of Homeland Security/FEMA

- The **Department of Homeland Security (DHS)** <u>issued</u> a weekly roundup of its response to COVID-19 on April 6 (New).
- **DHS** and **Department of Justice** <u>announced</u> on April 1 that they have extended the temporary postponement of Migrant Protection Protocols (MPP) hearings scheduled through May 1, 2020.
- 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 essential critical infrastructure workers.
- Federal Emergency Management Agency's (FEMA) coronavirus website visit here.
- FEMA will <u>issue</u> a temporary final rule on April 10 to restrict the export of five types of personal protective equipment (PPE) (New).
- FEMA <u>announced</u> (4/7/20) an initial set of grants, in this instance they have **awarded \$16.7 million in funding to Colorado to assist the state in its purchases** in March and April of Personal Protective Equipment (PPE) such as disposable gowns, masks, face shields, safety glasses and gloves, sanitizer, respirators, and ventilators to assist hospitals, medical clinics, city and county governments, and certain private-non-profits across the state (New).
- FEMA <u>issued</u> (3/31/20) a document summarizing best practices for Community Emergency Response Teams regarding COVID-19 operations (New).
- **FEMA Supply Chain Task Force** has developed a four-pronged approach to securing needed coronavirus supplies. The four prongs are Preservation, Allocation, Acceleration, and Expansion. The details on the March 30 plan can be found here. In a related move, the FEMA Coronavirus Pandemic Supply Chain Stabilization Task Force (a joint FEMA and HHS initiative) has released a fact sheet.
- FEMA has established **How to Help** <u>website</u> 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 submit a price quote under the <u>COVID-19 PPE and Medical Supplies Request for Quotation</u>. Full details can be found in the solicitation (<u>Notice ID 70FA2020R00000011</u>).
 - This solicitation requires registration with the System for Award Management (SAM) in order to be considered for award, pursuant to applicable regulations and guidelines. Registration information can be found at www.sam.gov. Registration must be "ACTIVE" at the time of award.
 - o 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.
 - If you are a hospital or healthcare provider in need of medical supplies, please contact your state, local, tribal or territory department of public health and/or emergency management agency.
 - If you are interested in doing business with FEMA and supporting the response to COVID 19 with your company's non-medical goods and/or services, please submit your inquiry



to the Department of Homeland Security (DHS) Procurement Action Innovative Response Team (PAIR) team at DHSIndustryLiaison@hq.dhs.gov.

• FEMA provides <u>guidance</u> (updated regularly) to <u>companies seeking to import or manufacture</u> 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.

Department of Justice/Federal Trade Commission

- On April 7, the **Drug Enforcement Agency** (DEA) <u>announced</u> that it was increasing quotas available to pharmaceutical manufacturers for the production of controlled substances in high demand due to COVID-19 (New).
- On April 1, the **Department of Justice** (DOJ) <u>announced</u> that it is making \$850 million available to **help public safety agencies** respond to the coronavirus pandemic.
- On March 23, President Donald Trump released an <u>Executive Order</u> 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 (3/26/20).
- On April 6, Ian Conner, the director of the Federal Trade Commission's (FTC) Bureau of Competition published a <u>blog post</u> about the importance of the agency "stay[ing] the course" when it comes to antitrust enforcement. Even as agency staff work remotely to review mergers and alleged anticompetitive conduct, Conner wrote, "We will not suspend our usual rigorous approach to ferreting out anticompetitive harm and seeking appropriate relief, even in the face of uncertainty. It might be tempting, for example, for parties to urge us to relax the rules in a time of crisis. But we know what the likely long-term negative consequences of such a reactionary policy would be: fewer competitors, reduced innovation, and higher prices." In particular, Conner emphasized the FTC will not lower its standards for evaluating who will be effective third-party buyers of businesses or assets required to be divested to resolve FTC merger investigations (New).
- On April 2, the FTC and FDA sent letters to three companies for selling fraudulent COVID-19 products, as part of the agencies' effort to protect consumers. (Letters available here, and here). This is the third time the FTC sent warning letters to companies for their actions related to the pandemic.
 - 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. Earlier in March, 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. For more information about this announcement, review this A&B summary (4/6/20) (New).
 - Coronavirus challenges grow for companies responding to issues like the new expedited government review process. For practical advice on avoiding antitrust risk, review this A&B <u>advisory</u>. (3/24/20)
 - The DOJ completed its first Business Review Letter under the new expedited review process on April 4, announcing that "it will not challenge collaborative efforts of McKesson Corporation, Owens & Minor Inc., Cardinal Health Inc., Medline Industries Inc., and Henry Schein Inc. to expedite and increase manufacturing, sourcing, and distribution of personal-protective equipment (PPE) and coronavirus-treatment-related medication."
 - In addition to the expedited BRL process, certain joint ventures and standard development organizations can also find some level of reduced antitrust risk through a seldomly used law—the National Cooperative Research and Production Act ("the NCRPA").
 - The DOJ filed its first <u>enforcement action</u> (3/21/20) against COVID-19 fraud, successfully obtaining a temporary restraining order against the operators of the website, "coronavirusmedicalkit.com."
- Understanding how federal agencies will review merger transactions during the coronavirus outbreak has business and legal implications. The A&B Mergers & Acquisitions Group <u>examines</u> (3/19/20) what you need to know.

Department of Labor / Equal Employment Opportunity Commission

- The **Equal Employment Opportunity Commission (EEOC)** confirmed (4/8/20) that it has "temporarily suspended the issuance of charge closure documents" including **right-to-sue notices** unless requested by the employee (**New**).
- The **Department of Labor (DOL)** provided <u>FAQs</u> further clarifying paid leave requirements under the new **Families First Coronavirus Response Act (FFCRA**).
 - On Sunday (4/5/20), DOL published <u>guidance</u> to states for the implementation of the **Pandemic Unemployment Assistance (PUA) program**. Under PUA, individuals who do not qualify for regulator unemployment compensation and are unable to continue working as a result of COVID-19, are eligible for up to 36 weeks of PUA benefits.

- The DOL <u>issued</u> (4/4/20) an unemployment insurance program letter explaining to state workforce agencies how to implement unemployment compensation provided for under the CARES Act (New).
- Last Friday, DOL released additional <u>guidance</u> which includes a comprehensive webinar explaining which employers are covered by the new law, which workers are eligible, and what benefits and protections the law provides. The **Wage and Hour Division (WHD) also added additional Questions and Answers** to its website in response to the questions most frequently received to-date through its extensive stakeholder engagement. Workplace posters translated into additional languages, which fulfill notice requirements for employers obligated to inform employees about their rights under the FFCRA, have also been added to WHD's website. To view the webinar and other guidance materials, visit here.
- A&B's Labor and Employment Group provides an overview of the FFCRA and an updated collection of responses to some of the most common questions about employer obligations in this <u>advisory</u> (3/31/20).
- The DOL posted (3/26/20) the required employee notice that must be provided by covered employers to their employees regarding the **new paid leave requirements** as required by the FFCRA. 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 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.
- **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:
 - OSHA <u>issued</u> (4/6/20) a new workplace poster on how to reduce the risk of exposure to coronavirus (New).
 - OSHA's enforcement <u>guidance</u> (4/3/20) on the use of respiratory protection equipment certified in other countries (New).
 - 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:
 - DOL has released additional questions and answers as guidance for the provisions required by FFCRA. A&B provides a complete <u>overview and analysis</u> (<u>updated</u> 4/7/20).

- **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.

Securities and Exchange Commission

- The Securities and Exchange Commission Chairman confirmed in a <u>statement</u> that the June 30, 2020 compliance date for the Regulation Best Interest (Reg BI) and Form CRS remains in effect. The A&B Financial Services & Products Group analyzes compliance with Reg BI and Form CRS mandates in this A&B <u>advisory</u> (4/2/20).
- The **SEC** issued an amended <u>order</u> (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.
 - The SEC issued (4/6/20) two compliance and disclosure interpretations (<u>here</u> and <u>here</u>) regarding eligibility for relief under the amended order (New).
 - The A&B Securities Group <u>examines</u> (3/27/20) the SEC's continued efforts to provide relief to filers whose filing obligations have been affected by the pandemic.
- 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 expects filers to disclose the known, likely to be known, and unknown risks they
 face during the coronavirus pandemic and to better prepare, read these A&B <u>questions</u>
 to ask yourself (3/30/20).
- 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).

Small Business Administration

- **Small Business Administration (SBA)** In response to the **CARES Act** requirements, the SBA formally <u>launched</u> its Paycheck Protection Program for small businesses on April 3.
- The SBA has guidance (4/1/20) for loans under the <u>Paycheck Protection Program</u>, the <u>Express Bridge Loan Pilot Program</u>, the <u>Economic Injury Disaster Loan Program</u> for qualified entities that are impacted by COVID-19. The application for its economic injury federal disaster loans can be found here.
 - On April 7, the SBA, in consultation with the Treasury Department, <u>published</u> Frequently Asked Questions addressing the Paycheck Protection Program (New).

- On April 2, the SBA released the <u>interim final rule</u> implementing the Paycheck Protection Program.
- The Paycheck Protection Program authorizes up to \$349 billion toward job retention and certain other expenses for small businesses and eligible nonprofit organizations, Veterans organizations, and Tribal businesses described in the Small Business Act, as well as individuals who are self-employed or are independent contractors, are eligible if they also meet program size standards.
- Complete details on the SBA CARES Act programs (Updated 4/4/20):
 - For a top-line overview of the program CLICK HERE
 - If you're a lender, more information can be found HERE
 - If you're a borrower, more information can be found HERE
 - PPP Borrower Application Form (Updated 4/2/20)
 - PPP Lender Application Form
 - PPP New Lender Application Form (Federally Insured Depository Institutions,
 Federally Insured Credit Unions, Farm Credit System Institutions)
 - Paycheck Protection Program Interim Final Rule
 - Paycheck Protection Program Interim Final Rule on Affiliation
 - Paycheck Protection Program Applicable Affiliation Rules
 - Find an eligible lender
 - Frequently Asked Questions
- For a deeper dive on the funding streams available for SBA loans in the CARES Act, review this A&B publication (4/1/20).
- Businesses large and small are navigating the chaotic economic climate; find some important actions you can take now to better prepare here (3/30/20), and for additional insights on lending and regulatory concerns, read this A&B advisory. (3/30/20)

Department of Treasury

- The Department of Treasury website for **CARES Act** programs.
- The Federal Reserve <u>announced</u> (4/6/20) that it will establish a facility to facilitate lending to small businesses under the SBA's Paycheck Protection Program (PPP) by **providing term financing backed by PPP loans** (New).
- Last Thursday, Treasury Secretary Steven Mnuchin and Small Business Administration
 Administrator Jovita Carranza announced that the interest rate on what lenders could charge
 small businesses for loans in the <u>Paycheck Protection Program</u> would be raised from 0.5% to 1%.
- The FFCRA gives businesses with fewer than 500 employees funds to provide employees with paid sick leave and family and medical leave related to COVID-19. On April 1, the Department of Treasury and IRS released FAQs regarding the tax credits available under this Act.
- On April 1, the Treasury Department and the IRS launched the Employee Retention Credit, designed to employees that have been financially impacted by COVID-19 can receive 50% of up to \$10,000 in wages paid.

- The **CARES Act** establishes a \$349 billion **Paycheck Protection Program** and on Tuesday the Department of Treasury jointly with the Small Business Administration announced the details. A brief overview and separate fact sheets for the lenders and the borrower can be found here.
- On Monday, the Treasury Department provided the <u>details</u> on the Economic Impact Payments program up to \$1,200 for individuals or \$2,400 for married couples. Parents also receive \$500 for each qualifying child. This program was also required by the **CARES Act**.
 - On Wednesday, the Department of Treasury and the IRS <u>announced</u> that **Social Security beneficiaries** who are not typically required to file tax returns will not need to file an abbreviated tax return to receive an Economic Impact Payment. Instead, payments will automatically be deposited into their bank accounts.
- The Treasury Department <u>announced</u> (3/31/20) it was **delaying tax payment** due dates for wine, beer, distilled spirits, tobacco products, firearms, and ammunition excise taxes, to provide flexibility for businesses that have been negatively affected by COVID-19. The postponement of due dates applies to any tax payment with an original due date falling on or after March 1, 2020, through July 1, 2020.
- 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.
 - To understand the federal regulators guidance on loan modifications and reporting, see this A&B <u>advisory</u>. (3/24/20)
- 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.
 - The CARES Act provides a refundable tax credit for businesses of all seizes that experience economic hardship due to COVID-19. <u>Click here</u> for A&B's guide to how the credit works.
 - The IRS has issued the following tax season guidance:
 - Coronavirus <u>Tax Relief</u>. (3/13/20)
 - IRS Operations During COVID-19: Functions continue guidance. (3/24/20)
 - Filing and payment deadlines <u>FAQs</u>. (3/13/20)

Other Agencies

The **Department of Transportation (DOT)** <u>issued</u> (4/7/20) a new rule regarding minimum service requirements and exemptions for **airlines** receiving financial assistance under the CARES Act (New).

- The **DOT Pipeline and Hazardous Materials Safety Administration (PHMSA)** <u>issued</u> (4/6/20) a notice of enforcement discretion regarding the filling of certain non-flammable gas cylinders to assist members of the medical and industrial gas industry (New).
- The DOT Federal Transit Administration (FTA) issued an <u>Enforcement Notice</u> on Friday clarifying airline refund requirements.
 - The DOT <u>announced</u> (4/2/20) \$25 billion in federal grant funding to help the nation's public transportation systems under the CARES Act.
 - The FTA issued (4/6/20) updated FAQs on the implementation of the CARES Act (New).
- The Federal Aviation Administration <u>issued</u> (4/4/20) FAQs on the \$10 billion in grants for airports provided under the CARES Act (New).
- The Consumer Financial Protection Bureau (CFPB), Federal Reserve, Federal Deposit Insurance
 Corporation (FDIC), the National Credit Union Administration (NCUA), the Office of the
 Comptroller of the Currency (OCC), and state banking regulators issued (4/3/20) a joint
 statement on supervisory and enforcement practiced regarding mortgage servicing rules
 regarding COVID-19 and the CARES Act. For additional details on the joint statement, review this
 A&B advisory (4/6/20) (New).
- The **Department of Housing and Urban Development (HUD)** <u>announced</u> (4/1/20) set of **mortgage payment relief** options for single family homeowners with FHA-insured mortgages who are experiencing financial hardship as a result of the coronavirus pandemic. Mortgage servicers are instructed to:
 - Offerforbearance—deferred or reduced mortgage payment options—for up to six months to affected borrowers;
 - Delay submitting Due and Payable requests for Home Equity Conversion Mortgages by six months; and
 - Extend any flexibility they may have under the Fair Credit Reporting Act relative to negative credit reporting actions.
- The **Department of Education (DOE)** released a <u>proposed regulation</u> on Thursday (4/2/20) amending eligibility requirements for faculty and student interactions in online college programs. Members of the public will have 30 days to submit comments on the Education Department's proposal before it issues a final rule.
 - The Department of Education also <u>announced</u> (3/31/20) new federal deadline flexibility for Career and Technical Education leaders.
- The **United States Copyright Office** <u>announced</u> (4/6/20) that in addition to previously announced extensions, it would provide emergency relief for mechanical royalty payments and notice requirements under Section 115 of the Copyright Act with respect to copyright owners who previously received these items in paper format (New).
- On March 31, the **U.S. Patent and Trademark Office (USPTO)** announced extensions to the time allowed to file certain <u>patent</u>-related and <u>trademark</u>-related documents and to pay certain required fees. For additional details on this topic, review this A&B advisory (4/2/20).
- The **Department of Veterans Affairs (VA)** <u>announced</u> on April 3 that financial relief actions would be extended to veterans with COVID-19, include suspending all actions on Veteran debts under the jurisdiction of the Treasury Department and suspending collection action or extending repayment terms on preexisting VA debts, as the Veteran prefers.

- The VA released a <u>statement</u> (3/31/20) that veterans continue to receive benefits and services after the Veterans Benefits Administration (VBA) temporarily closed its <u>56</u> regional offices to the public in response to COVID-19.
- The Department of Agriculture (USDA) Rural Development Division has launched a <u>resource</u>
 <u>page</u> to help rural residents, farmers, and businesses stay current on the Agency actions related
 to COVID-19.
 - On Friday, the Rural Development Division <u>announced</u> it was opening a second application window for the Distance Learning and Telemedicine Grant program funding.
- 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 <u>here</u>. (3/23/20)
- **Construction Industry**: The coronavirus pandemic creates special problems for the construction industry which include site safety and contractor and subcontractor responsibilities for such. These issues and more are examined in this A&B advisory.
 - 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

- The World Trade Organization director-general announced (4/6/20) that export controls don't make sense in a pandemic fight. Imposing export controls on medical supplies and forcing the full domestication of supply chains will do more harm than good in fighting the COVID-19 pandemic, World Trade Organization Director-General Roberto Azevêdo said on Monday, chastising countries for looking inward instead of focusing on multilateral cooperation to address the global crisis. In a joint statement, Azevêdo and World Customs Organization Secretary General Kunio Mikuriya said they would "work closely together to minimize disruption to cross-border trade in goods" and provide needed support to "all relevant stakeholders." (New)
- Lawmakers Seek Info on Medical Imports. Two top Congressional lawmakers called yesterday
 for an International Trade Commission investigation to identify imported products needed
 during the COVID-19 pandemic and what kind of tariffs they face. House Ways and Means
 Committee Chairman Richard Neal (D-Mass) and Senate Finance Committee Chairman Chuck
 Grassley (R-Iowa) asked the ITC to provide a report by April 30 detailing the tariff classifications
 and applicable rates of duty associated with the products to assist the committees in their work
 to combat the emergency (New).
- Trump Unveils Deal With 3M To End Mask Production "Saga." President Donald Trump announced Monday the end of a "saga" involving his administration and 3M Co., which had pushed back against White House requests to stop exporting medical grade masks amid the coronavirus pandemic. Under a deal unveiled at the president's daily coronavirus press briefing, 3M will import 166.5 million masks to the U.S. over the next three months from its facility in China while continuing to send U.S.-produced masks to Canada and Latin America (New).

Insurance Issues

- Some auto insurers are voluntarily returning some money to customers as the widespread government shutdowns result in a decline in driving as people shelter at home (New).
- A <u>Pandemic Risk Insurance Act</u>, modeled after the TRIA, has been under consideration by the U.S. House Financial Services Committee since Mid-March. Thus far, a draft bill is unavailable.
- Rhode Island is the latest state to follow the Louisiana, New York, New Jersey, Massachusetts, and Ohio proposals that would re-write business interruption coverage to force insurance companies to cover businesses that have shut down due to the novel coronavirus pandemic and, at least in some cases, override express policy exclusions for infectious diseases or virus contamination (New).
- On March 25, Washington joined other state lawmakers, including those in California and New York, in <u>requiring insurers</u> to: (1) submit data regarding the volume of business interruption coverage, contingent business interruption coverage, and supply chain coverage written by the insurer that was in effect as of March 15, 2020; (2) explain the coverage each policy provides relating to COVID-19; and (3) provide an explanation of benefits to policyholders and the Commissioner's office. Responses are due on or before April 1, 2020.
- New York City and <u>New Orleans</u> have both issued civil authority shutdown orders that explicitly provide that COVID-19 may spread from "surface to person... causing property loss and damage in certain circumstances." These provisions appear calculated to provide future litigants with a plausible hook to argue for business interruption coverage where such coverage is contingent on the existence of "physical damage."
- The West Virginia Insurance Commissioner published a <u>bulletin</u> on March 26, 2020 explaining that though **business interruption policies** are governed by contract law that may vary state-by state, they "were generally not designed or priced to provide coverage against communicable diseases, such as COVID-19, and therefore usually include exclusion for that risk." The Commissioner directs insureds and policyholders to contract their insurer regarding availability of coverage, and explicitly prohibits insurers from reporting "negative claims activity or a claim denial when an insured or policyholder contacts the company or its agent or broker to inquire about business interruption coverage for COVID-19 under its policy."
- New lawsuits have been filed against insurers regarding business interruption coverage for claims arising out of the COVID-19 pandemic. These suits follow several other similar actions filed in South Carolina, Louisiana, Oklahoma, California, Texas and Illinois (Updated 4/8/20)
 - On April 3, 2020, Restaurant Nicholas filed suit against Liberty Mutual Insurance in New Jersey Superior Court seeking a declaratory judgment from the court that Liberty Mutual is obligated to pay for business interruption losses under business income, extra expense, and civil authority coverages. Restaurant Nicholas's attorney indicated that they have not yet filed a claim with Liberty Mutual.
 - Also on April 3, 2020, the Indiana Repertory Theatre Inc. brought suit against its insurer,
 The Cincinnati Casualty Company in Indiana state court. Indiana Repertory seeks a
 declaratory judgment ruling that the insurer is required to cover damages sustained as a
 result of being forced to close in connection with the COVID-19 pandemic.

On April 6, 2020 Sandy Point Dental PC filed suit against its insurer, The Cincinnati
Insurance company in the U.S. District Court for the Northern District of Illinois. Sandy
Point alleges that its insurer wrongfully denied its claims for business interruption losses
incurred because the State ordered it to stop most of its operations.

Additional Workplace (Stay-at-Home) Issues

- Government Closure/Stay-at-Home orders have been released in multiple state and local jurisdictions.
 - For the key Stay-at-Home order details in one document, view this A&B <u>COVID-19 50-State Closure Tracker</u> (<u>Updated 4/6/20</u>).
 - o To date, the **only states that have not issued state-wide stay-at-home orders** are Arkansas, Iowa, Oklahoma, Nebraska, North Dakota, South Dakota, Utah, and Wyoming.
 - For 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.
 - 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.

Cyber Security & Privacy

- **Government contractors and Federal employees** are part of the newly remote workforce. The Department of Defense has issued new <u>guidance</u> (4/2/20) for its workers.
- The COVID-19 pandemic provides an opening for a variety of malicious cyber-attacks. The **FBI** details threats and ways to protect yourself (4/1/20)
 - Go Video teleconferencing is the new normal for the remote workforce. But is it secure?
 The FBI offers tips (3/30/20) on how to protect yourself from being hijacked.
 - This A&B <u>advisory</u> (4/7/20) discusses the current COVID-19 cybersecurity threat landscape, including scams that target individuals, attempts to compromise company systems, telework vulnerabilities, and business email compromise (New).
- 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.

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 and additional resources visit the joint Commission Coronavirus <u>website</u>.

• The Joint Commission released a <u>statement</u> for healthcare workers regarding the use of face masks brought from home.

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:

- 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</u> Under Investigation in Healthcare Settings
- 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 20
 - Employee Benefits & Executive Compensation Advisory: Coronavirus Impact on Health Benefits: A Deeper Dive
 - FDA Compliance & Enforcement Advisory: FDA Temporarily Postpones Routine
 Domestic Inspections
 - March 19
 - Antitrust / Mergers & Acquisitions Advisory: COVID-19 Impacts Antitrust Deal Reviews: New Procedures and Delays
 - Construction Advisory: Five Best Practices for Construction Industry Stakeholders
 During the Coronavirus Pandemic
 - <u>Labor & Employment Advisory: Employee Leave Requirements Under the Families</u>
 <u>First Coronavirus Response Act</u>

<u>Labor & Employment / Health Care Advisory: Coronavirus (COVID-19) FAQs for Employers</u>

March 18

- Cyber Alert: Six Practical Tips for Practicing Cyberhygiene in the Middle of a Global Pandemic
- Advisory: Are You an "Essential Business" in California Counties Where Shelter-in-Place Order Have Benn Issued?

March 17

Finance Advisory: Coronavirus and Securitization: Disclosure and Diligence Issues

o March 16

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

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
- <u>Securities Litigation Advisory: Securities Litigation Risk Arising Out of the</u>
 Coronavirus Pandemic

o March 12

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

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

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>