Coronavirus Flash Update: Friday, April 10, 2020

The Latest News

- U.S. COVID-19 cases exceed 463,619 and 16,695 U.S. deaths. (Source: CDC)
- U.S. stock market: Thursday ended with the major U.S. benchmarks up for the second consecutive day, with the Dow gaining 285 points, the S&P up 39 points, and the Nasdaq rising 62 points.
- On Thursday, the Department of Labor released in its weekly unemployment report that claims reached 6.6 million last week bringing the two week total to nearly 17 million.
- Today, the Department of Health and Human Services (HHS) began distributing the initial $30 billion in COVID-19 relief funding to providers as part of the distribution of the $100 billion fund provided for the Public Health and Social Services Emergency Fund (PHSSEF) through the CARES Act. This initial distribution of funds will go to hospitals and providers currently enrolled in Medicare and take effect immediately. Facilities and providers are allotted a portion of the $30
billion based on their share of 2019 Medicare fee-for-service (FFS) reimbursements. These are payments, not loans, and will not need to be repaid. Fund recipients will be prohibited from balancing billing COVID-19 patients for related services. HHS is partnering with UnitedHealth Group to deliver the initial $30 billion provider distribution and providers will be paid via Automated Clearing House account information on file with UnitedHealth Group, UnitedHealthcare, or Optum Bank, or used for reimbursements from CMS. Additional details can be found here. (New)

- A second phase of targeted distributions to providers is expected to follow soon and will focus on providers in areas particularly impacted by the COVID-19 outbreak, rural providers, and providers of services with lower shares of Medicare FFS reimbursement or who predominantly serve the Medicaid population.
- CMS also announced yesterday that it had approved over $51 billion in accelerated or advance payments for Medicare providers in its first week.

- The Centers for Disease Control and Prevention announced on April 9 an extension of its “No Sail” order for all cruise ships for at least 100 days. (New)

- On Thursday an attempt to pass Senate Majority Leader Mitch McConnell’s (R-KY) proposal for an additional $250 billion in small business loan funding failed to receive the unanimous consent needed to pass, and an alternative proposal offered by Senate Democrats also failed. The Majority Leader’s proposal proposed to boost funding for the Paycheck Protection Program (PPP) and other small business aid authorized in the CARES Act two weeks ago. The Senate Democratic alternative proposal also included $250 billion in additional small business aid and included $100 billion in aid for hospitals and other healthcare providers and $150 billion additional funding for states, tribes, and local communities. The alternative proposal also included a 15 percent increase in the Supplemental Nutrition Assistance Program (SNAP). Negotiations will continue and a consensus proposal could be reached as early as this weekend. (New)
  - These attempts to boost the funding for small business loans and in several other programs are already being tagged relief bill 3.5 and are separate from the work on a larger, more comprehensive relief bill, 4.0, which remains underway.

COVID-19 Related Legislation

- Bill 4.0: Despite the side bar action this week to seek quick approval for an additional $250 billion in small business assistance as well as health care provider funding and other items 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. The failure to quickly enact a supplemental 3.5 bill, does not auger well for the negotiations on a larger 4.0 package later this month.

- Bill 3.0: Coronavirus Aid, Relief, and Economic Security (CARES) Act, (H.R. 748) passed on March 27.
  - 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 Educational Provisions and Appropriations
- **A&B Guide** – how the CARES Act refundable Employer Retention tax credit for employers works
- **A&B Hospital Provisions Tracking Document** 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

- Congress has passed three coronavirus emergency response bills and the first two are below:
  - **Bill 1.0**: Coronavirus Preparedness and Response Supplemental (CPPRS) *(H.R. 6074)* passed on March 5.
  - **Bill 2.0**: Families First Coronavirus Response Act (FFCRA) *(H.R. 6201)* passed on March 18.

- A new interactive (free) webpage which tracks how state legislatures and regulatory agencies are responding to the coronavirus epidemic, including pending bills, new regulations, and executive orders. *(New)*

### Key Administrative and Regulatory Actions

- The White House unveiled *(4/7/20)* 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.

- **President Trump** invoked the Defense Production Act last week *(4/2/20)* for the 3rd time in ten days, ordering a ban on exports by 3M Co. of scarce supplies, including N95 respirators, surgical masks, and gloves.
  - Earlier last week, the President ordered 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** declared *(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 DPAS training Course 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 executive order (3/30/20) to order up to 1 million Ready Reserve 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 draft (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 here.

Environmental Protection Agency

- On April 3, Environmental Protection Agency (EPA) Administrator Wheeler outlined steps to protect against fraudulent disinfectant claims.
- The EPA identified (4/7/20) approximately 225,000 pieces of personal protection equipment they will donate to state and local responders.
- On April 2, the EPA revised List N: Disinfectants for Use Against SARS-CoV-2 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 allow (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 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 allowing 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, Coronavirus and Drinking Water and Wastewater, 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.
- The FCC provided relief 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 program 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 COVID-19 Telehealth Program. The Wireline Competition Bureau will review applications, select participants, make funding awards on a rolling basis, and will announce such information.
  - The FCC provided guidance (4/8/20) to address common application questions. (New) There are steps interested providers can take immediately to prepare to apply for the COVID-19 Telehealth Program:
    1. Obtain an eligibility determination by filing an FCC Form 460 with the Universal Service Administrative Company (USAC) (Applicants can still
submit an application for the COVID-19 Telehealth Program while the Form 460 application is pending;
2. Register to obtain an FCC Registration Number (FRN) in the Commission Registration System (CORES); and register with System for Award Management in order to receive funding.
   ▪ To apply, applications must be submitted through the FCC’s Electronic Comment Filing System (ECFS), inputting “20-89” in the “Proceeding(s)” box and completing the form, including the required information described in the Report and Order.
   o The FCC also provided additional details on the Connected Care Pilot Program. 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.
      1. 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

• The Department of Health and Human Services (HHS) has unveiled a COVID-19 Resources page.
• Pursuant to the President’s Executive Order, (3/25/20), HHS announced its initial list 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 posted a new tracking feature that allows public viewing of all COVID-19 HHS grant and cooperative agreement awards on its website at https://taggs.hhs.gov/coronavirus. The initial grants were distributed through programs in the Agency for Community Living, Centers for Disease Control and Prevention, National Institutes of Health, and Office for the Assistant Secretary for Emergency Preparedness. (New)
• The HHS Office of Inspector General (HHS-OIG) issued (4/3/20) a policy statement regarding the application of previously issued blanket waivers to Anti-Kickback Statute sanctions.
   o 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.

- 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 Health Care Advisory analyzing each category of waivers.

- HHS announced on Tuesday it is purchasing the ID NOW COVID-19 rapid point-of-care test for state, territorial and tribal public health lab use.

- The HHS Office of Civil Rights (OCR) released a notification (4/9/20) that it will exercise its enforcement discretion and will not impose penalties for violations of the HIPAA Rules against covered entities or business associates in connection with the good faith participation in the operation of COVID-19 testing sites during the COVID-19 nationwide public health emergency. This exercise of enforcement discretion is effective immediately but has a retroactive effect to March 13, 2020. (New)

- The HHS OCR announced (4/2/20) that it will exercise its enforcement discretion and will not impose penalties for violations of certain provisions of the HIPAA Privacy Rule 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 notice is effective immediately.

- The HHS Office of the Assistant Secretary for Health announced new guidance authorizing pharmacists to order and administer COVID-19 tests.

Assistant Secretary for Preparedness and Response

- ASPR announced (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 supply chain, fatality management, and emergency departments.

Centers for Disease Control and Prevention

- For the most up to date CDC guidance visit here. The CDC has also added a series of Training for Health Professionals webinars.

- The CDC released new guidance (4/9/20) advising that critical infrastructure workers may be permitted to continue work following potential exposure to COVID-19, provided they remain asymptomatic and additional precautions are implemented to protect them and the community. A potential exposure means being a household contact or having close contact within 6 feet of an individual with confirmed or suspected COVID-19. The timeframe for having contact with an
individual includes the period of time of 48 hours before the individual became symptomatic. (New)

- **The CDC issued** (4/7/20) guidance for businesses and buildings on how to ensure that **water systems are safe to use after prolonged shutdowns**.
- **The CDC updated** (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.
- **The CDC has released a report** (4/7/20) on **COVID-19 illness in children** which includes topline findings on diagnosing and treating children with COVID-19.
- **HHS announced** (4/6/20) that the CDC would provide **$186 million in funding** to state and local jurisdictions to respond to COVID-19.
- For **pharmacy** staff, the CDC has posted **information** on strategies to minimize risk of exposure.
- **The Centers for Disease Control and Prevention announced** 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 recommendations** (4/3/20) on **optimizing the supply of PPE**.
  - The CDC also released **guidance** on the collection and submission of postmortem specimens from deceased person with COVID-19, and last week multiple new areas of **information** 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 **health care professionals** and one for **hospitals**.

**Centers for Medicare & Medicaid Services**

- **On April 9**, **CMS temporarily suspended** a number of rules—effective immediately—so that hospitals, clinics, and other health care facilities can boost their frontline medical staffs. (New)
  - As a result of CMS’s action:
    - Doctors can now directly care for patients at rural hospitals, **across state lines** if necessary, **via phone, radio, or online communication**, without having to be physically present. Remotely located physicians, coordinating with nurse practitioners at rural facilities, will provide staffs at such facilities additional flexibility to meet the needs of their patients.
    - Nurse practitioners, in addition to physicians, may now perform some medical exams on Medicare patients at **skilled nursing facilities** so that patient needs, whether COVID-19 related or not, continue to be met in the face of increased care demands.
    - Occupational therapists from **home health agencies** can now perform initial assessments on certain homebound patients, allowing home health services to start sooner and freeing home-health nurses to do more direct patient care.
    - **Hospice nurses** will be relieved of hospice aide in-service training tasks so they can spend more time with patients.
  - CMS also **released** a fact sheet including additional information on the waivers announced on April 9. (New)
CMS has created a website location for COVID-19 stakeholder call recordings and transcripts, and the most recent daily CMS COVID-19 news alert can be found here (updated 4/9/20). The number of CMS conference calls and webinars keep a steady pace:
  o CMS held a COVID-19 Update call on Tuesday and provided a slide presentation summarizing recent action.
  o CMS released a video (4/2/20) on the common questions regarding Medicare’s telehealth services benefit.
CMS issued (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.
The Agency announced on Tuesday it had approved 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.
A new COVID-19 ICD-10 diagnosis code was announced by CMS and is effective April 1.
CMS updated (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.
CMS issued 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 explained in a summary included with the announcement.
On April 2, CMS issued recommendations to nursing homes and state and local governments on infection control in long term care. The recommendations include:
  o Nursing homes should immediately ensure that they are complying with all CMS and CDC guidance related to infection control.
  o 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.
  o Nursing homes should immediately implement symptom screening for all staff, residents, and visitors – including temperature checks.
  o Nursing homes should ensure staff are using appropriate PPE, to the extent PPE is available and per CDC guidance on conservation of PPE.
CMS announced on March 30 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 on individuals and entities that provide health care services to Medicare beneficiaries during the COVID-19 public health emergency. Comments are due not later than June 1, 2020.
On April 9, CMS issued FAQs regarding this interim final rule. (New) See this A&B Summary for the key details of the Interim Final Rule. (4/8/20) (New)

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 release. 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)
    - List of Blanket Waivers (4/3/20)
    - 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)
      - IFC Federal Register Announcement (4/1/20)
    - Graphic Overview of Flexibilities (PDF)
    - Provider Burden Relief Frequently Asked Questions (PDF)
    - Provider Enrollment Relief Frequently Asked Questions (PDF)
    - 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 here.
    - 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 advisory (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 information bulletin (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 advisory (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:
1. CMS issued an electronic toolkit regarding telehealth and telemedicine for Long Term Care Nursing Home Facilities (3/28/20)
2. CMS telehealth FAQs (3/17/20)
3. HHS 1135 HIPAA waiver factsheet - HIPAA Security Rule safeguards
4. HHS Notice of Enforcement Discretion factsheet
5. HHS Office of Civil Rights bulletin
6. Guidance on Business Associate Agreements
   - The CARES Act required CMS to expand its accelerated and advance payment program, and on March 28 a statement and fact sheet were released providing guidance on the policy. For additional analysis, read this A&B advisory (3/30/20) on the CMS guidance.
   - CMS announced 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.
   - CMS, on behalf of Vice President Mike Pence, sent a letter (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 memorandum (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 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.
     - CMS has approved 49 coronavirus 1135 waivers, and for more details and the full list CMS approved 1135 waivers can be found here. And on March 27, CMS announced the approval of 16 state hospital associations in one letter (it can be found here and additional information.)
   - The National Uniform Billing Committee has provided guidance on claims for COVID-19 treatment and approved the use of DR (disaster related) condition code for services related to the coronavirus.
   - On March 25, CMS announced 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:
     - Medicare Provider Enrollment Relief FAQs (see: FAQs).
     - CMS posted guidance on Payment and Grace Period Flexibilities for issuers offering coverage on the federally-facilitated exchanges and state-based exchanges on the federal platform (see: guidance).
     - CMS announced it will be exercising enforcement discretion so QHP issuers and SADPs can extend payment deadlines for initial binder payments and ongoing premium payments. CMS released FAQs on availability and usage of telehealth through private health insurance (see: FAQs).
CMS released FAQs on prescription drugs and COVID-19 for health insurance issuers in individual and small group markets (see: FAQs).

CMS announced (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:
- On April 2, CMS updated their Medicaid FAQs.
- CMS posted notice (3/24/20) that it had withdrawn its proposed rule to tighten Medicaid eligibility determination.
- CMS released guidance (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 template.

CMS announced (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 advisory (3/24/20).

Food and Drug Administration

- FDA provides a daily roundup on COVID-19 related actions (4/9/20) a listing of all announcements.
  - The agency published a public database of drug shortages.
- FDA is hosting virtual town hall events for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SARS-CoV-2 to help answer questions. (New). The town halls will be hosted on the following dates:
  - April 15, 2020 from 12:15pm – 1:15pm EST
  - April 22, 2020 from 12:15pm – 1:15pm EST
  - April 29, 2020 from 12:15pm – 1:15pm EST
- FDA and FTC continue to issue Warning Letters to sellers of fraudulent COVID-19 products for prevention for COVID-19, including CBD products. FDA also issued a warning letter (4/8/20) to a seller that markets fraudulent and dangerous chlorine dioxide products. (New)
- FDA has updated its EUA from April 3, 2020, applicable to Chinese manufacturers of PPEs. The number of listed Chinese manufacturers increased from 2 to 8. (New)
- FDA has put out a factsheet on best practices for retail food stores, restaurants, and food pick-up and delivery services during the COVID-19 pandemic. This includes information on managing
employee health, personal hygiene for employees, appropriate food safety protocols, and special safety considerations for pick-up and delivery. A visual summary info graph is also available. (New)

- FDA released (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.
  - And FDA issued (4/6/20) an FAQ from members of the animal food industry on COVID-19.
- FDA issued (4/5/20) an FAQ on 3D printing of medical devices and other equipment during the COVID-19 pandemic.
- Last Friday (4/3/20), the FDA announced 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 guidance (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 emergency use authorizations 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 announced (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 ventilators and accessories, 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.
  - The FDA updated its FAQs (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 strategies to assist in the conservation of masks and gowns, as well as glove conservation strategies.
- On March 27, the FDA issued guidance on notifying FDA of permanent discontinuation or interruption in manufacturing.
  - For further analysis, see this A&B advisory (4/9/20). (New)
- 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 USDA FSIS and FDA 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 issued, “FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic,” to assist sponsors in assuring the continued safety of trial participants, while minimizing risks to trial integrity, and maintaining compliance with good clinical practices (GCPs) during the pandemic. Included in the new guidance are the options for phone contact and virtual visits in clinical trials.

Health Resources and Services Administration

• On April 8, HHS, through the Health Resources and Services Administration (HRSA) awarded more than $1.3 billion that had been allocated under the CARES Act to 1,387 health centers as part of the COVID-19 pandemic response. HRSA-funded health centers may use the awards to help communities across the country detect coronavirus; prevent, diagnose, and treat COVID-19; and maintain or increase health capacity and staffing levels to address this public health emergency. The list of recipients is available here. (New)

• HRSA updated its FAQs (4/2/20) for health centers with additional questions to address the Federal Tort Claims Act among other flexibilities that have been enacted.
  o HRSA awards (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 guidance (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) issued a weekly roundup of its response to COVID-19 on April 6.

• DHS and Department of Justice announced on April 1 that they have extended the temporary postponement of Migrant Protection Protocols (MPP) hearings scheduled through May 1, 2020.

• DHS announced (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 guidance (3/28/20) on essential critical infrastructure workers.

• Federal Emergency Management Agency’s (FEMA) coronavirus website visit here.

• FEMA issued an advisory on April 9 regarding the option to transition federal Community-Based Testing Sites (CBTS) to state management. (New)
• FEMA will issue a temporary final rule on April 10 to restrict the export of five types of personal protective equipment (PPE).

• FEMA announced (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.

• FEMA issued (3/31/20) a document summarizing best practices for Community Emergency Response Teams regarding COVID-19 operations.

• 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 website for individuals and organizations interested in helping the effort to combat the spread of COVID-19. Examples of assistance offered include:
  o To sell medical supplies or equipment to the federal government, please submit a price quote under the COVID-19 PPE and Medical Supplies Request for Quotation. Full details can be found in the solicitation (Notice ID 70FA2020R00000011).
    ▪ 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 provide us details on what you are offering.
  o If you have a private company that wants to produce a product related to the COVID-19 response – email nbeoc@max.gov.
  o 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.
  o 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 guidance (updated regularly) to companies seeking to import or manufacture medical products to the COVID-19 response. A list of FEMA regional private sector contacts and state contacts can be found here.

  Department of Justice/Federal Trade Commission

• On April 9, the Federal Trade Commission (FTC) provided guidance to remind education technology providers and schools about their continued obligations to protect student’s privacy and safeguard their personal data under the Children’s Online Privacy Protection Act (COPPA) as
well as the Family Educational Rights and Privacy Act (FERPA) during the coronavirus pandemic. (New)

- From January 1, 2020 through April 8, 2020, the FTC has reported receiving more than 14,227 COVID-19 related complaints with a total fraud loss of $10.04 million with a median fraud loss of $564. (New)

- On April 7, the Drug Enforcement Agency (DEA) announced that it was increasing quotas available to pharmaceutical manufacturers for the production of controlled substances in high demand due to COVID-19.

- On April 1, the Department of Justice (DOJ) announced 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 Executive Order on hoarding and price gouging of critical COVID-19 supplies. For guidance and tips on how businesses can respond if they are victims of price gouging, read this A&B advisory (3/26/20).

- On April 6, Ian Conner, the director of the Federal Trade Commission’s (FTC) Bureau of Competition published a blog post 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.

- 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, 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 letters to nine VoIP providers 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 warning letters to seven companies about unsupported claims that products can treat or prevent Coronavirus.

- The FTC Chairman Joe Simons issued a statement (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: business.covid@ftc.gov, noting FTC staff would respond to inquiries as quickly as possible.

- On March 25, the FTC released business guidance 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).

  - 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 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 enforcement action (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 examines (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.

- The Department of Labor (DOL) provided FAQs further clarifying paid leave requirements under the new Families First Coronavirus Response Act (FFCRA).

  - On Sunday (4/5/20), DOL published guidance 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 issued (4/4/20) an unemployment insurance program letter explaining to state workforce agencies how to implement unemployment compensation provided for under the CARES Act.
Last Friday, DOL released additional guidance 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 advisory (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 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 effective date of the new leave requirements.

• DOL released a statement (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 issued (4/6/20) a new workplace poster on how to reduce the risk of exposure to coronavirus.
  o OSHA’s enforcement guidance (4/3/20) on the use of respiratory protection equipment certified in other countries.
  o OSHA’s practical guidance (3/21/20) to prevent the spread of COVID-19
  o OSHA’s COVID-19 website
  o Wage and Hour Division (WHD) guidance (3/24/20) on Families First Coronavirus Response Act (FFCRA): Employee Paid Leave Rights
  o Trying to make sense of all these changes? A&B provides brief overviews of what you need to know:
    o DOL has released additional questions and answers as guidance for the provisions required by FFCRA. A&B provides a complete overview and analysis.

• DOL/OSHA updated its website, 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.
  o Large employers are assessing policies and potential liability to ensure a safe and secure workplace. The CDC has released (updated 3/21/20) guidance for employers related to employee information on COVID-19.

Securities and Exchange Commission

• The Securities and Exchange Commission (SEC) issued updated guidance (4/7/20) on conducting shareholder meetings in light of COVID-19 concerns. See the A&B advisory for a discussion of the guidance initially issued on March 13. Additionally, the State of Delaware issued an executive
order (4/6/20) that facilitates companies’ notice of a change in the format of an annual shareholder meeting by allowing notification to stockholders via an SEC filing and press release. (New)

- The SEC Chairman confirmed in a statement 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 advisory (4/2/20).

- The 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.
  - The SEC issued (4/6/20) two compliance and disclosure interpretations (here and here) regarding eligibility for relief under the amended order.
  - The A&B Securities Group examines (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 Topic No. 9 (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 questions to ask yourself (3/30/20).

- The SEC also issued a statement (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 advisory (3/26/20).

Small Business Administration

- Small Business Administration (SBA) – In response to the CARES Act requirements, the SBA formally launched its Paycheck Protection Program for small businesses on April 3.

- The SBA has guidance (4/1/20) for loans under the Paycheck Protection Program, the Express Bridge Loan Pilot Program, the Economic Injury Disaster Loan Program for qualified entities that are impacted by COVID-19. The application for its economic injury federal disaster loans can be found here.
  - On April 8, the SBA, in consultation with the Treasury Department, updated its published FAQs addressing the Paycheck Protection Program. (Updated 4/8/20)
  - On April 2, the SBA released the interim final rule 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 (Updated 4/8/20)

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)

A&B’s Financial Restructuring & Reorganization Group has provided proactive steps creditors can take now to prepare for whatever comes after the coronavirus pandemic subsides in this advisory. (4/9/20). (New)

Department of Treasury

- The Department of Treasury website for CARES Act programs.
- The Federal Reserve announced (4/9/20) that it will launch a lending program for mid-sized businesses hurt by the coronavirus, called the Main Street Lending Program. The new program will provide up to $600 billion in loans to eligible businesses through two facilities. (New)
  - A brief overview and comparison of the two Main Street programs can be found here. (New)
- The Federal Reserve provided details for the provision of up to $2.3 trillion in loans to support the economy on April 9. (New)
  - Term Sheet: Term Asset-Backed Securities Loan Facility (PDF)
  - Term Sheet: Secondary Market Corporate Credit Facility (PDF)
  - Term Sheet: Municipal Liquidity Facility (PDF)
  - Term Sheet: Main Street Expanded Loan Facility (PDF)
  - Term Sheet: Primary Market Corporate Credit Facility (PDF)
  - Term Sheet: Paycheck Protection Program Lending Facility (PDF)
  - Term Sheet: Main Street New Loan Facility (PDF)
- The Department of Treasury, Federal Reserve, and FDIC jointly announced (4/9/20) an interim final rule to encourage lending to small businesses through the SBA’s Paycheck Protection Program (PPP). (New)
• The Federal Reserve Board announced (4/8/20) that it will temporarily modify the growth restrictions on Wells Fargo so that it can provide additional support to small businesses. (New)
• The Federal Reserve announced (4/6/20) that it will establish a facility to facilitate lending to small businesses under the PPP by providing term financing backed by PPP loans.
• 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 Paycheck Protection Program 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 encourage businesses to keep employees on their payroll. Eligible employers 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 details 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.
  o On Wednesday, the Department of Treasury and the IRS announced 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 announced (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 committed (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 advisory (3/27/20) reviews the three main laws that govern electronic signatures.
• In a joint statement (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 The federal financial institution regulatory agencies issued a revised interagency statement providing additional information regarding loan modifications on April 7. (New)
  o To understand how federal regulators are clarifying the CARES Act interaction with previous statements on loan modifications and reporting read this A&B advisory. (4/9/20). (New)
• 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 April 9, the IRS extended additional tax deadlines for estates, individuals, and businesses until July 15, 2020. As a result, the extensions generally now apply to all taxpayers that have a filing or payment deadline falling on or after April 1, 2020, and before July 15, 2020. (New)
- The CARES Act provides a refundable tax credit for businesses of all sizes that experience economic hardship due to COVID-19. Click here for A&B’s guide to how the credit works.
- The IRS has issued the following tax season guidance:
  - Coronavirus Tax Relief. (3/13/20)
  - IRS Operations During COVID-19: Functions continue guidance. (3/24/20)
  - Filing and payment deadlines FAQs. (3/13/20)
- Responding to requests for relief from the Real Estate Roundtable and others, the IRS issued Revenue Procedure 2020-23 on April 8 to address technical issues that would have limited the ability of partnerships and their partners to benefit from retroactive CARES Act provisions. (New)
  - For a deeper dive on this topic, see this A&B advisory (4/9/20). (New)

**Other Agencies**

- The Department of Transportation (DOT) issued (4/7/20) a new rule regarding minimum service requirements and exemptions for airlines receiving financial assistance under the CARES Act.
- The DOT Pipeline and Hazardous Materials Safety Administration (PHMSA) issued (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.
- The DOT Federal Transit Administration (FTA) issued an Enforcement Notice on Friday clarifying airline refund requirements.
  - The DOT announced (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.
- The Federal Aviation Administration issued (4/4/20) FAQs on the $10 billion in grants for airports provided under the CARES Act.
- 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 practices 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).
- The Department of Housing and Urban Development (HUD) announced (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:

- Offer forbearance—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 announced on April 9 that more than $6 billion will be distributed
  immediately to colleges and universities to provide direct emergency cash grants to college
  students whose lives and educations have been disrupted by the coronavirus outbreak. The
  funding is available through the Higher Education Emergency Relief Fund authorized by the
  CARES Act. (New) Additional details can be found in this FAQs on Dept. of Education grant funds.

  - The Department of Education also released a proposed regulation on April 2 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 announced (3/31/20) new federal deadline flexibility
    for Career and Technical Education leaders.

- The United States Copyright Office announced (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.

- On March 31, the U.S. Patent and Trademark Office (USPTO) announced extensions to the time
  allowed to file certain patent-related and trademark-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) announced 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 statement (3/31/20) that veterans continue to receive benefits and
    services after the Veterans Benefits Administration (VBA) temporarily closed its 56
    regional offices to the public in response to COVID-19.

- The Department of Agriculture (USDA) Rural Development Division has launched a resource
  page to help rural residents, farmers, and businesses stay current on the Agency actions related
  to COVID-19.
  - The Rural Development Office has posted a fact sheet of funding opportunities for rural
    residents, businesses and communities. (4/8/20) (New)
  - On Friday, the Rural Development Division announced 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 letter (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)

- 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

- Temporary FEMA rule will ban export of some medical equipment without approval. Some medical equipment needed to combat COVID-19 cannot be exported from the U.S. without the “explicit approval” of the Federal Emergency Management Agency, according a new rule set to take effect this week. The “temporary final rule” will be effective from April 10 through mid-August, according to a Federal Register notice set to be published officially on Friday. (New)
- European Commission provides antitrust guidance. On April 8, the European Commission published a “Temporary Framework Communication” to provide antitrust guidance to companies co-operating in response to urgent situations related to the current coronavirus outbreak. The European Commission also issued a rare “comfort letter” concerning a specific co-operation project aimed at avoiding situations of shortages of critical hospital medicines. This appears to correspond to the expedited DOJ / FTC business review / informal opinion letters. (New)
- Customs to seize exports of masks and gloves amid coronavirus pandemic. U.S. Customs and Border Protection (CBP) announced Wednesday it will prevent respirators, surgical masks and surgical gloves from leaving the country. The Federal Emergency Management Agency (FEMA) will then determine if the equipment should be returned, purchased by the government or exported. The announcement comes days after President Trump invoked the Defense Production Act (DPA) to stop the flow of critical equipment outside of the country. See joint statement of CBP and FEMA here. (New)
- WTO offers bleak outlook for 2020 as countries take drastic measures to fight pandemic. The economic recession sparked by the pandemic is likely to be the worst in a generation, according to a World Trade Organization report released on Wednesday, with global merchandise trade expected to plunge as much as 32 percent this year. See the full outlook here. (New)
- WCO, WHO Issue Updated COVID-19 Medical Supplies Classification Guide. The World Customs Organization, with help from the World Health Organization, updated its list of tariff classifications for COVID-19 medical supplies, the WCO said in a news release to cover a greater range of medical equipment and supplies that are required as critical items by the WHO. (New)
- Grassley Supports Tariff Deferral and Zero Tariffs on Medical Goods Needed for Crisis. The leaders of the congressional committees that oversee trade policy have asked the International Trade Commission to organize a list of all goods that relate to the response to the COVID-19 pandemic, with their tariff rates, any additional tariffs, and any tariff exclusions on those goods. (New)
potential agency actions to reduce supply chain slowdowns related to the COVID-19 pandemic, the FMC said in an April 6 news release. (New)

- **DEA Adjusts 2020 Quotas for Controlled Substances in Response to COVID Pandemic.** The Drug Enforcement Administration is adjusting 2020 production quotas for controlled substances in schedule II of the Controlled Substances Act, as well as quotas for the manufacture and importation of the Schedule I chemicals ephedrine, phenylpropanolamine and pseudoephedrine. “This increase is in response to the current nationwide COVID-19 public health emergency,” the DEA said. (New)

### Insurance Issues

- More auto insurers have joined in voluntarily returning some money to customers as the widespread government shutdowns result in a decline in driving as people shelter at home.
- A Pandemic Risk Insurance Act, 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. (updated 4/10/20)
- Pennsylvania and South Carolina are the latest states to follow the Rhode Island, 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. Pennsylvania’s bill has bipartisan support from 37 members of the House. (New)
- 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 New Jersey, Indiana, South Carolina, Louisiana, Oklahoma, California, Texas and Illinois (Updated 4/10/20)
  - On April 8, 2020, Somco LLC dba J3 Clothing Company filed suit against Lightning Rod Mutual Insurance Company Ohio state court seeking a declaratory judgment from the court that it is entitled to business interruption coverage for losses associated with the coronavirus pandemic and executive orders issued by the Governor of Ohio.
  - On April 7, 2020, Sharecropper LLC dba Ollie Irene filed suit against its insurer Farmers Insurance Exchange Inc. dba Farmers Insurance in Alabama state court. Plaintiff alleges that it was forced to close to dine-in services as a result of the coronavirus pandemic and Farmer’s denied its claim for business interruption coverage. Plaintiff seeks a declaration that its losses are covered losses under its policy.
  - On April 6, 2020, Mace Marine Inc., the owner and operator of Conch Republic Dive Shop in the Florida Keys brought suit against its insurer Tokio Marine Specialty Insurance Co. in Florida state court. Mace Marine alleges that the insurer breached the policy when it denied business interruption coverage for claims pertaining to losses arising out of the coronavirus pandemic.
Additional Workplace (Stay-at-Home) Issues

- The CDC released new guidance (4/9/20) advising that critical infrastructure workers may be permitted to continue work following potential exposure to COVID-19, provided they remain asymptomatic and additional precautions are implemented to protect them and the community. A potential exposure means being a household contact or having close contact within 6 feet of an individual with confirmed or suspected COVID-19. The timeframe for having contact with an individual includes the period of time of 48 hours before the individual became symptomatic. (New)

- Following the CDC’s recommendation of wearing face coverings as “additional, voluntary public health measure,” we are seeing a trend of local government orders mandating the use of facemasks or cloth face coverings in public and/or the workplace. (New)
  - Examples include several counties and municipalities in Southern California (including the City of Los Angeles), Hoboken, New Jersey, and Texas counties.
  - Most mandate use by individuals when in public, but at least one local government (Los Angeles) is requiring employers to provide the face coverings for their employees.
  - Most orders are careful not to require the use of surgical or N-95 face masks, which should be reserved for medical responders.
  - We expect to see the trend of mandating the use of face coverings in public to spread to other local, and perhaps state, governments.

- 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 COVID-19 State Closure Tracker. (Updated 4/9/20)
  - 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.
  - 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 advisory (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 outlines (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 guidance (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 advisory (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.

- 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 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 website.
  - The Joint Commission released a statement for healthcare workers regarding the use of face masks brought from home.

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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
Infection Prevention and Control Recommendations for Patients with COVID-19 or Persons Under Investigation in Healthcare Settings

Information for Laboratories

Resources for First Responders

Guidance for Public Health Professionals Managing People with COVID-19 in Home Care and 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)

- 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
  - Labor & Employment Advisory: Employee Leave Requirements Under the Families First Coronavirus Response Act
  - Labor & Employment / Health Care Advisory: Coronavirus (COVID-19) FAQs for Employers

- 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 Been Issued?

- March 17
  - Finance Advisory: Coronavirus and Securitization: Disclosure and Diligence Issues

- March 16

- March 13
  - 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

- March 10
  - Labor & Employment / Health Care Advisory: Coronavirus, Employers, and 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](#)
  o **February 28**
  ▪ [Labor & Employment / Health Care Advisory: The Coronavirus: Employer and Workplace Considerations](#)