Federal Issues
Legislative

Trump Signs Paycheck Protection Program Changes
On Friday, President Trump signed into law several changes to the Paycheck Protection Program (PPP) on Friday after the Senate cleared the legislation by voice vote earlier in the week.

Why it Matters: As states begin to reopen, the changes will give greater flexibility to small businesses as they consider the best strategies for hiring back employees.

Key changes to the PPP in the legislation:
- Reduces the amount of the loan that must be spent on payroll from 75% to 60%;
- Extends the time period to spend the loan from 8 weeks to 24 weeks;
- Extends the re-hire deadline to December 31, 2020 and changes the rehire requirements; and
- Extends the repayment term from two to five years.

Coronavirus Hearings Break Out On Capitol Hill
Last week saw more than a dozen Congressional committees hold COVID-19 related hearings on
Capitol Hill, examining various aspects of the pandemic and its impact on American life. The list:

- Governor Carney Announces Phase 2 of Delaware’s Economic Reopening to Begin on June 15

Pennsylvania

Legislative
- State False Claims Proposal Scheduled for House Committee Vote

Regulatory
- All Pennsylvania Counties Now in the Yellow or Green Phase of Reopening

West Virginia

Regulatory
- West Virginia Strong – the Comeback Enters Weeks Six

- Senate Health Education Labor and Pensions Committee -- COVID-19: Going Back to College Safely.
- Senate Finance Committee -- COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process.
- Senate Small Business and Entrepreneurship Committee -- Perspectives from Main Street: COVID-19's Impact on Small Business.
- Senate Banking, Housing and Urban Affairs Committee -- Implementation of Title IV of the CARES Act.
- Senate Environment and Public Works Committee -- Infrastructure: The Road to Recovery.
- Senate Veterans Affairs Committee -- Review of the FY 2021 Budget and FY 2022 Advance Appropriations Request and Oversight of CARES Act Supplemental Appropriations for the Department of Veterans Affairs.
- House Financial Services Committee -- Promoting Inclusive Lending During the Pandemic: Community Development Financial Institutions and Minority Depository Institutions.
- House Budget Committee -- Addressing the Economic Impacts of COVID-19: Views from Two Former CBO Directors.
- Committee on House Administration -- The Impact Of COVID-19 On Voting Rights And Election Administration: Ensuring Safe And Fair Elections.
- House Judiciary Committee -- Protecting the Right to Vote During the COVID-19 Pandemic.
Both chambers will be back in action this week with additional hearings and behind-the-scenes work on the fourth coronavirus legislative package. Timing remains uncertain, with speculation beginning to mount that the Senate will not take up its next package before July.

### Court Hears Arguments in Medicaid MCO Health Insurance Tax Lawsuit

On June 1, oral arguments were held in *Texas v. United States* - the lawsuit filed by attorney generals from six states challenging the inclusion of the ACA health insurance tax (HIT) in Medicaid managed care organizations’ (MCOs) capitation rates for years prior to 2018.

**Why it matters:** The Fifth Circuit appeal filed by the federal government seeks to overturn a series of decisions made by Judge Reed O’Connor in the U.S. District Court for the Northern District of Texas. Those decisions invalidated certain HHS regulations requiring states to include the HIT in Medicaid MCOs’ capitation rates and awarded nearly $480 million to be equitably disgorged (refunded) by the federal government to the six plaintiff states for any related HIT amounts they may have paid over the relevant period.

Arguments presented at Monday’s hearing were heard by a three-judge panel and were consistent with those made by the parties in their earlier briefing. The Judges pressed both sides on issues regarding which parties are or are not responsible for paying the HIT, the meaning and application of actuarial soundness under federal law, questions regarding Administrative Procedure Act processes, and the appropriateness of equitable disgorgement as a remedy.

**Timing:** While the court gave no indication of when it would issue a decision, observers believe it will most likely rule before the end of the year.

### Stakeholders Urge Congress to Increase Medicaid Support

A coalition of 20 leading health care organizations sent a letter to Congressional leaders, urging them to increase the Federal Medical Assistance Percentage (FMAP) for the Medicaid program. The coalition calls on Congress to enhance federal financing for the Medicaid program by at least 12 percentage points, with additional support for those states hardest hit by COVID-19. This increase should be extended until states’ economic recovery is secure and stable, consistent with the requests outlined by the bipartisan National Governors Association.

**Why this matters:** The letter emphasizes the COVID-19 pandemic will likely result in shortfalls in state revenues, forcing state leaders to enact deep Medicaid cuts, which could cause millions of Americans to lose access to critical health care services.

### Stakeholders Urge Congress to Remove Prohibition on Federal Funding for National Patient Identification System

AHIP and other health care stakeholders sent letters to House and Senate Appropriation Committee leaders urging the removal of legislative language that prohibits the Department of Health and Human Services (HHS) from spending any federal dollars to promulgate or adopt a national unique patient identifier.
(UPI). The language was included in the Fiscal Year 2021 Labor, Health and Human Services, and Education and Related Agencies (Labor-HHS) Appropriations bill.

The letter states that removing the prohibition on the use of federal funds to adopt a national UPI will provide HHS "the ability to evaluate a range of patient identification solutions and enable it to work with the private sector to explore potential challenges and identify a solution that protects patient privacy and is cost-effective, scalable, and secure."

AHIP has encouraged the Department to continue to facilitate private industry innovation to advance patient matching solutions.

Federal Issues
Regulatory

AHIP Responds to CMS RFI on Rural Maternal and Infant Health
AHIP submitted comments to the Centers for Medicare & Medicaid Services’ (CMS) Office of Minority Health (OMH) regarding their request for information (RFI) on opportunities to improve health care access, quality, and outcomes for women and infants in rural communities, before, during, and after pregnancy.

AHIP highlighted several actions health insurance providers’ are taking to increase rural emergency medical services (EMS) and hospital capacity, address racial and ethnic disparities, social determinants of health, and improve health care quality and health outcomes. AHIP also provided recommendations for the Administration on reducing regulatory burden and expanding health and wellness programs and community-based efforts to address the issues faced by expecting or new mothers and their children.

Why this matters: Over the last 2 years, AHIP has been actively involved in the areas of rural and maternal and child health. The COVID-19 pandemic has only served to highlight the disparities in care for people living in rural areas and many of the disparities underlying the crisis of maternal morbidity and mortality.

IRS Rule Would Implement Excise Tax on Certain Executive Compensation
The Internal Revenue Service (IRS) issued a proposed rule implementing a provision of the Tax Cuts and Jobs Act of 2017 that imposed a 21% excise tax on certain executive compensation paid by tax-exempt organizations.

Under the proposed rule, any deferred compensation arrangement or retention or retirement bonus not vested prior to the first taxable year beginning after December 31, 2017 is subject to the tax.

The IRS will accept comments on the proposed rule for 60 days after its publication in the June 11 Federal Register.

Why this matters: There is already a rigorous process prescribed by the IRS for setting up executive compensation. The process requires an impartial panel drawn primarily from the board of trustees, which is charged with setting CEO compensation based on the marketplace and documenting deliberations to attract the best talent.
The American Hospital Association will continue to advocate for an exception for existing contracts or nonqualified deferred compensation plans for applicable tax-exempt organizations.

**CMS Issues Guidance on Optional Medicaid COVID-19 Testing Coverage**

The Centers for Medicare & Medicaid Services (CMS) released guidance on June 2 for states implementing the Medicaid Optional Uninsured COVID-19 Testing (XXIII) Group, established by the Families First Coronavirus Response Act.

States can use this new optional Medicaid eligibility group to access federal funds to cover the full cost of COVID-19 testing-related services for uninsured individuals.

See CMS’s previous guidance for more detailed information on eligibility requirements, benefits and federal matching rates for coverage under the optional COVID-19 testing group.

**Summary of key provisions:**

- **Enrollment:** States can develop a simplified application for the new COVID-19 testing eligibility group to minimize burden on the applicant. States also are encouraged to assess whether individuals found ineligible for the state’s Medicaid program can be covered through the COVID-19 testing eligibility group. States must verify citizenship and immigration status, using available federal systems. If such verification systems are not immediately available, states may conduct verification post-enrollment.

- **Hospital-based Presumptive Eligibility (HPE):** States can request to include the COVID-19 eligibility testing group as a group covered under HPE through their disaster state plan amendment.

- **Reporting and Provider Claims:** In order for states to receive the increased federal funding for this eligibility group, states must meet a continuous coverage requirement. As such, states must ensure that the individuals do not need to apply again for coverage of any subsequent testing.

- **Coordination between Medicaid Uninsured Option for COVID-testing and HRSA COVID-19 Claims Reimbursement Program for Uninsured:** States choosing the Medicaid COVID-19 testing option must coordinate benefits with the Health Resources & Services Administration (HRSA) COVID-19 claims reimbursement program.

**Why this matters:** The guidance outlines flexibilities available to states to pay for COVID-19 testing for uninsured individuals.

**Federal COVID-19 Policy Guidance and Other Developments**

HHS released guidance requiring labs to report detailed information on coronavirus testing, including patient information like race, ethnicity, age, ZIP code, and the type of test used. Beginning August 1, data must be provided to relevant state or local public health departments within 24 hours, which then will send data to the Centers for Disease Control and Prevention (CDC) daily.

House Labor, Health and Human Services, Education (LHHS) Appropriations Subcommittee held a hearing “COVID-19 Response” with Centers for Disease Control and Prevention (CDC) Director Dr. Robert Redfield as the sole witness. Dr. Redfield testified to several areas of need in public health,
including public health data modernization, public health laboratory capacity, contact tracing, testing, and COVID-19 related health disparities in the African American and Latinx community.

The Government Accountability Office (GAO) published a COVID-19 model to help guide major policy decisions, such as how to allocate health care resources in the COVID-19 response.

CMMI Issues Summary of COVID-19-related Adjustments for Alternative Payment Models: The Center for Medicare and Medicaid Innovation announced several COVID-19-related modifications to current and future CMMI alternative payment models. The adjustments are captured in a summary table and are related to the models’ financial methodologies, quality reporting requirements and timelines.

Additional $250 Million Released for Health Systems’ COVID-19 Response: The Department of Health and Human Services said it is providing an additional $250 million to aid health systems’ response to the COVID-19 pandemic. The funding, which was authorized by the Coronavirus Aid, Relief, and Economic Security Act, adds to the $100 million initially disbursed in April by the HHS Office of the Assistant Secretary for Preparedness and Response.

Of the $250 million in CARES Act funding being provided, $125 million will be distributed through cooperative agreements with hospital associations in all 50 states, the District of Columbia, Puerto Rico, and New York City. The other $125 million will be distributed through the Hospital Preparedness Programs’ cooperative agreements with 62 state and local public health departments. The funding also advances the mission of the National Special Pathogen System to enhance national capacity and capability to respond to highly infectious diseases now and in the future.

FDA Reissues Respirators EUAs with New Decontamination-for-Reuse Instructions: The Food and Drug Administration reissued emergency use authorizations that revise the policy on the types of respirators that can be decontaminated for reuse. Citing a response to public health concerns, FDA determined that certain respirators should not be decontaminated for reuse by health care professionals during the COVID-19 public health emergency.

CMS Issues COVID-19 Guidance for Non-federal Governmental Plans: The Centers for Medicare & Medicaid Services Friday released guidance for non-federal governmental plans implementing the Families First Coronavirus Response Act requirement to cover COVID-19 diagnostic testing and certain related items and services without cost-sharing, prior authorization or other medical management restrictions during the public health emergency. The guidance also covers the relaxed enforcement of certain timeframes related to group market requirements, and expanding and promoting access to telehealth options and prescription drugs during the outbreak.

FDA Issues Guidance on Non-invasive Monitoring Devices: The Food and Drug Administration Friday released new guidance that expands for the duration of the COVID-19 emergency the availability and capability of non-invasive monitoring devices. This replaces guidance issued March 20, and includes additional device types and offers more references and standards. The FDA said remote devices reduce patient and health care provider contact, ultimately limiting possible COVID-19 exposure.

CMS Accepting Applications for Direct Contracting Model Through July 6: Eligible hospitals can apply through July 6 to participate in the Medicare Direct Contracting Model, which will offer two primary care payment options for hospitals beginning next April. The model is open to hospitals that employ clinicians as well as to critical access hospitals and rural health clinics.
CMS has postponed the implementation period for aligning beneficiaries, which will start in October rather than July. Hospitals accepted to participate in the model can defer their start date and participate with the model’s second cohort in January 2022 if they choose.

**FDA Posts Testing Resources and Approves Drug for Ventilated Patients:** The Food and Drug Administration released COVID-19 performance data for four more antibody test kits. The results come from the first collaboration between FDA, the National Institute of Health’s National Cancer Institute, Centers for Disease Control and Prevention and Biomedical Advanced Research and Development Authority.

Meanwhile, a [new video](#) from the FDA explains for the public the different categories of COVID-19 tests, such as tests for those currently infected versus those with antibodies.

On June 3, the FDA also approved a new [sedation injection](#) for intubated and ventilated patients in intensive care settings and non-intubated patients prior to or during surgical and other procedures. The drug’s most common side effects are hypotension, bradycardia, and dry mouth.

**HHS Issues Guidance on COVID-19 Laboratory Data Reporting:** The Department of Health and Human Services [released guidance](#) specifying what data laboratories must report to HHS along with their COVID-19 test results, the method for submission, and the data reporting and transmission requirements. HHS will require all laboratories to report results for each test completed within 24 hours of results for each individual tested. The Coronavirus Aid, Relief, and Economic Security Act requires laboratories that test for COVID-19 or the SARS-CoV-2 virus to report the results to HHS.

According to the guidance, laboratories generally should send the data to state or local public health departments using existing reporting channels to ensure case investigations begin rapidly.

**FDA Issues Guidance on Requirements for Individual Requests to Use COVID-19 Investigational Drugs:** The Food and Drug Administration [last week released guidance](#) for institutional review boards seeking clarity regarding the key factors and procedures they should consider when reviewing requests by physicians and others for individual patient access to investigational drugs.

A request for emergency individual patient access to an investigational drug does not require prior IRB review, but the board must be notified within five working days once treatment begins and any subsequent use of the drug is subject to IRB review, the guidance notes.

**Study Estimates Impact of Various Social Distancing Scenarios:** Social distancing interventions started earlier in the COVID-19 epidemic appear to delay the epidemic curve while interventions started later appear to flatten it, according to a [new study](#) published in the Centers for Disease Control and Prevention’s Emerging Infectious Diseases Journal.

Noting that sustaining social distancing interventions over several months might not be feasible economically and socially, the authors said their models suggest that “a combination of social distancing interventions, testing, isolation, and contact tracing of new cases is needed to suppress transmission of SARS-CoV-2.”

**FDA Launches COVID-19 Webpage for Health Professionals:** The Food and Drug Administration recently created an [online compendium page](#) of COVID-19 resources for health care professionals. The
FDA has indicated it will regularly update the page, which provides useful information on several issues, including emergency use authorizations, personal protective equipment and medical products, including investigational drugs and fraudulent devices.

**NASA Earns Emergency Authorization for Second Ventilator; Fitbit-designed Offering Also Approved:** The Food and Drug Administration has **authorized** the emergency use of two new products designed to respond to the COVID-19 ventilator shortage. The FDA approved the NASA's second VITAL ventilator. Like NASA's first iteration of the device, VITAL is designed to last three-to-four months using components sourced from outside the current medical device supply chain. Unlike NASA’s first ventilator, VITAL uses an internal compressor as its energy source, rather than wall gas. Meanwhile, the Fitbit Flow earned an FDA emergency use authorization as an emergency resuscitator. The Fitbit Flow is a continuous respiratory support system that includes an FDA-cleared, Ambu-designed manual resuscitator bag with audible and visual alarms. By pairing the actuator with a manual resuscitator, health care professionals can use the device to support patients’ respiratory needs when no FDA-cleared clinical ventilators are available.

**CDC Updates COVID-19 Webpage to Clarify Types of Spread:** The Centers for Disease Control and Prevention **updated its page** on COVID-19 transmission to clarify other types of spread beyond person to person, such as by someone touching a surface that has the virus on it and then touching their face. The CDC notes that some people without symptoms may be able to spread the virus and that it is still learning how the virus spreads and the severity of illness it causes. The update is in response to media reports that suggested a change in CDC’s view on transmissibility. The web update is intended to make the CDC’s content easier to read and not a result of any new science.

**FDA Updates Policy to Spur Hand Sanitizer Availability:** The Food and Drug Administration **updated guidance** to spur wider availability of alcohol-based hand sanitizers during the COVID-19 pandemic. The agency’s temporary guidance clarifies interim levels of certain impurities that can be present in the ethanol used to produce alcohol-based hand sanitizer products during the public health emergency.

The FDA encourages consumers, manufacturers or distributors to email their questions regarding hand sanitizers to **COVID-19-Hand-Sanitizers@fda.hhs.gov** or review the **agency’s FAQs**.

**CMS Announces New Actions Regarding Nursing Home Infection Control:** The Centers for Medicare & Medicaid Services **implemented** several new infection control actions to combat COVID-19 in nursing homes. One action addresses the inconsistent rate of nursing home inspections mandated by CMS on March 4, which currently range from 11% to 100% across the states. State survey agencies that fail to inspect all nursing homes by July 31 will be required to submit a corrective action plan or have their federal funds under the Coronavirus Aid, Relief, and Economic Security Act redistributed to compliant states.

Another action expands penalties for nursing home deficiencies, which range from directed plans of correction to civil monetary penalties, with more significant actions for nursing homes with a history of past deficiencies or that cause actual harm or immediate jeopardy to residents. The agency also is deploying additional technical assistance resources to nursing homes, which will focus on the approximately 3,000 low-performing nursing homes with a history of infection control challenges.

**Campaign Targets Drug Maker Price Hikes:** The Campaign for Sustainable Rx Pricing, for which the American Hospital Association is a founding member, recently launched a petition and digital ad urging drug companies to suspend their “traditional” summer price hikes, which last year averaged 13%, saying the industry is thriving while Americans are struggling financially.
HHS announced a task order, worth approximately $628 million, with Emergent BioSolutions to advance manufacturing capabilities and capacity for a potential COVID-19 vaccine as well as therapeutics. The National Governors Association (NGA) sent a letter to state Governors outlining recommendations and planning considerations for dealing with simultaneous emergencies, such as natural disasters and COVID-19.

State Issues

Delaware
Regulatory

State of Emergency Extended
On June 6, 2020 Governor John Carney formally extended the State of Emergency declaration in place to limit the spread of COVID-19. Under Delaware law, State of Emergency declarations must be renewed every 30 days.

Governor Carney Announces Phase 2 of Delaware’s Economic Reopening to Begin on June 15
Governor Carney announced that Phase 2 of Delaware’s economic reopening will begin on Monday, June 15. On Monday, June 8, personal care service businesses may open at 30% of stated fire occupancy. Private instruction, such as tutoring services, testing centers, adult education, or specific vocational training facilities (outside of traditional K-12 structures) may resume.

The general guidance for individuals is consistent with prior guidance (wear cloth face coverings, wash hands, social distance), with the following updates:

- The new (Phase 2) limit for indoor gatherings will be 50 people, with the directive to social distance from those not part of your household;
- In Phase 2, locations currently operating at 30% of fire occupancy requirements can move to 60% of fire occupancy requirements (excluding staff). Exercise facilities and personal care services (hair care, tanning, tattoo, massage therapy services, nail care, brow care, spas, waxing services, and similar) are to remain at 30% of fire occupancy requirements;
- Fully unenclosed outdoor gatherings of up to 250 people are permitted if public health precautions are in place to protect against spread of COVID-19;
- Leisure travel should be avoided, but may resume as long as general guidance is strictly adhered to by all commercial lodging facilities; and
- All vulnerable individuals are directed to continue to shelter in place. Members of households with vulnerable residents should be aware that by returning to work or other environments where distancing is not practical, they could carry the virus back home. Precautions should be taken to isolate from vulnerable residents.

The Governor continues to encourage employers to continue to have staff work from home whenever possible. Employees who have been working from home throughout the crisis should continue working from home unless there is a substantive change to business operations in Phase 1. Click here to read the full guidance.
State Issues

Pennsylvania
Legislative

State False Claims Proposal Scheduled for House Committee Vote
The House Human Services Committee has scheduled several bills for consideration on Tuesday, June 9 that would combat health care fraud in the Medicaid program. One of the proposals, House Bill 2352, would create a state False Claims Act.

Also on the Committee’s agenda:
- **House Bill 2355** – Requires Medicaid Managed Care Organizations (MCOs) providing services to enter into an agreement with the Department of Human Services (DHS) to authorize the recovery of any loss incurred as a result of an organization’s failure to comply with contract terms, comply with federal or state Medicaid regulations, and cease payment under a provider preventable condition (PPC).
- **House Bill 2350** – Requires individuals seeking to provide goods or services reimbursable under Medicaid to register with DHS and obtain a State Provider Identifier (SPI). Each claim submitted must include the NPI or SPI of the individual providing the goods or service. Also requires enrollment in standardized training program.
- **House Bill 2351** – Increases penalties for submitting fraudulent claims against the Medicaid program – felony of the second degree for claims $100,000 or more; felony of third degree for claims between $2,000 and $100,000; and third degree misdemeanor for claims $2,000 or less.

Regulatory

All Pennsylvania Counties Now in the Yellow or Green Phase of Reopening
Twelve more counties in Pennsylvania will enter the green phase of Governor Tom Wolf’s reopening plan this Friday. Adams, Beaver, Carbon, Columbia, Cumberland, Juniata, Mifflin, Northumberland, Union, Wayne, Wyoming, and York counties are all designated to move out of the yellow phase at 12:01 A.M. on June 12. Every county in the state is now either in the yellow or the green phase after the Governor’s stay at home order expired on June 5.

Almost everything can reopen in the green phase, but Pennsylvania Department of Health and CDC guidelines must be followed. And, the green phase still has restrictions in place, such as but not limited to:
- Continued telework strongly encouraged;
- Businesses with in person operations must follow updated business and building safety requirements;
- All Businesses operating at 50% occupancy in the yellow phase may move to 75% occupancy;
- Prison and hospital restrictions continue;
- Large recreational gatherings remain restricted;
- Restaurants and bars open at 50% occupancy;
• Personal care services may reopen at 50% occupancy and by appointment only;
• Health and wellness facilities may reopen at 50% occupancy with appointments strongly encouraged; and
• All entertainment facilities, casinos and indoor malls may reopen at 50% occupancy.

State Issues

West Virginia
Regulatory

West Virginia Strong – the Comeback Enters Weeks Six
West Virginia's reopening plan continues to move forward, entering Weeks 6 and 7:

Week 1: Thursday, April 30 – Sunday, May 3 (underway)
Week 2: Monday, May 4 – Sunday, May 10 (underway)
Week 3: Monday, May 11 – Sunday, May 17 (underway)
Week 4: Monday, May 18 – Sunday, May 24 (underway)
Week 5: Monday, May 25 – Sunday, May 31 (underway)
Week 6: Monday, June 1 – Sunday, June 7 (underway)
Week 7: Monday, June 8 – Sunday, June 14 (underway)
Week 8: Monday, June 15 – Sunday, June 21
Week 9: Monday, June 22 – Sunday, June 28
Week 10: Monday, June 29 – Sunday, July 5

As of Friday, June 5, permitted purely social gathering size was increased from 25 to 100 individuals.

Opening Friday, June 5, 2020:
• Casinos
• Bingo Halls
• Movie theaters

Details on opening businesses and shopping
Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: http://legis.delaware.gov/
Pennsylvania Legislation: www.legis.state.pa.us
West Virginia Legislation: http://www.legis.state.wv.us/
For copies of congressional bills, access the Thomas website – http://thomas.loc.gov/

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