Federal Issues
Legislative

Congress Returns Amid COVID-19 Upswing
Congress returns from a two week break this week to begin putting together the next COVID-19 relief package, with the goal of sending a bill to President Trump by the first week in August. Democrats are using the HEROES Act, passed by the U.S. House in May, as their starting point for negotiation. Senate Republicans are reportedly putting together a much smaller package.

House Committee Passes Health Bills
Despite the recess, Congressional committees remained active with the House Energy and Commerce (E&C) Committee meeting Wednesday to consider 30 bills, including several healthcare proposals.

Among the bills advanced by the committee were:
- The Beneficiary Enrollment Notification and Eligibility Simplification (BENES) Act, which would improve beneficiary outreach and education, reduce gaps in coverage and simplify the Part B enrollment process.

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- The Protecting Patients Transportation to Care Act, which would include non-emergency medical transportation (NEMT) in the list of mandatory Medicaid benefits, codifying current Medicaid NEMT regulations. The bill would also require state Medicaid programs to have in place a utilization management process for the benefit.

Ways and Means Democrats Release Report Health Equity
Democrats on the House Ways and Means Committee released a report, titled “Left Out: Barriers to Health Equity for Rural and Underserved Communities” that analyzes the barriers to health care in rural and underserved communities.

Report highlights include:
- From 2008 to 2016, in Medicaid expansion states the uninsured rate dropped sharply from 35 to 16% in small and rural towns. In non-expansion states the decline was just six points, from 38 to 32%;
- In rural America, the rates of commercial insurance coverage are lower and the proportion of people eligible for Medicaid is higher than in urban localities;
- Thirty-nine percent of the population in rural areas lack access to broadband;
- Stark racial and ethnic disparities persist in key outcome measures, such as infant and maternal mortality and life expectancy; and
- Half of all states have experienced a 100 – 300% growth in the number of people for whom English is not their first language.

Federal Issues
Regulatory
Federal COVID-19 Policy Guidance and Other Developments

Families USA released a report on the number of health insurance losses as a result of the COVID-19 pandemic and the resulting economic repercussions. The report estimates that because of job losses between February and May of this year, 5.4 million laid-off workers became uninsured.

The Department of Health and Human Services (HHS) made May and June COVID-19 Testing Plans from all states, territories, and localities publicly available on HHS.gov. The plans include details on how states are responding to the surge in COVID-19 cases and how to reach vulnerable populations including minorities, immunocompromised individuals and older adults. AHIP has been working with other interested organizations to encourage states to leverage the funds appropriated through the previous COVID relief packages to support public health surveillance and occupational safety testing. AHIP will continue to advocate at the state and federal level to secure public funding for these purposes.

HHS recently announced a new telehealth initiative designed to help ambulatory providers learn how to use the technology. HHS and the Assistant Secretary for Preparedness and Response (ASPR) are partnering with the ECHO Institute at the University of New Mexico and the Public Health Foundation’s TRAIN Learning Network to launch a ten-week, virtual peer-to-peer learning community called Telemedicine Hack.

Supplementing the Tri-agency FAQs released on June 23, HHS developed a summary chart of the federal government’s coverage requirements of COVID-19 testing by private insurance plans. It also covers uninsured coverage questions on COVID testing.

The Centers for Medicare & Medicaid Services (CMS) issued guidance to state Medicaid agencies informing them that the agency will be extending the deadline for ensuring compliance with the Home and Community-Based Settings (HCBS) Regulation, in response to the COVID-19 pandemic. CMS has extended the compliance deadline for this regulation to March 17, 2023.

Pair of COVID-19 Vaccine Candidates Move on to Next Trial Phases: A COVID-19 trial vaccine developed by the University of Oxford and AstraZeneca produced neutralizing antibody responses in patients with SARS-CoV-2, according to a study published July 20 in The Lancet. An immune response was detected in 32 of 35 participants after a booster dose.

The trial will now proceed to phases two and three. Oxford/AstraZeneca in May announced it will provide the U.S. with 300 million initial doses and the U.K. 100 million initial doses this fall.

In a separate vaccine study by CanSino Biologics, a phase two test in Wuhan, China, showed an immunity response in 508 participants. The study said healthy adults may only need one dose, while older adults may need two to induce a better immune response. Results showed minimal adverse reactions; the candidate will now move to phase three testing.

Dexamethasone Study Shows Promising Results for Treating COVID-19 Patients: The New England Journal of Medicine last week released a study showing that the use of dexamethasone resulted in a lower, 28-day mortality rate among patients receiving invasive ventilation or oxygen.
The study indicated lower incidence of death among 2,104 patients treated with dexamethasone, compared to 4,321 patients receiving usual care. However, results showed very little impact in patients not receiving respiratory support.

The Food and Drug Administration also recently updated its COVID-19 treatment guidelines for corticosteroids, including dexamethasone. FDA said such drugs can be used for up to ten days in patients requiring supplemental oxygen, but not with those who are mechanically ventilated or do not require supplemental oxygen.

**FDA Greenlights New COVID-19 Tests and Anti-coagulant Drug:** The Food and Drug Administration last week reissued its emergency use authorization of Quest Diagnostics’ SARS-CoV-2 rRT-PCR test for use with pooled samples containing up to four individual swab specimens collected under observation.

The Quest test is the first COVID-19 diagnostic test to be authorized for use with pooled samples, which FDA said is an important public health tool because it allows for more people to be tested quickly using fewer testing resources.

FDA also authorized the emergency use of a pair of qualitative tests for detecting SARS-CoV-2 antibodies and nucleic acids. Boston Heart Diagnostics’ molecular Boston Heart COVID-19 RT-PCR Test and Luminex Corporation for its serology xMAP SARS-CoV-2 Multi-Antigen IgG Assay are approved for use for the duration of the COVID-19 public health emergency.

Finally, the agency approved an abbreviated new drug application for anti-coagulant heparin sodium. FDA says the drug, which prevents blood clotting, will help meet increased demand for such products during the COVID-19 public health emergency.

**HHS Announced Second Provider Relief Fund Distributions to Hot Spot Hospitals:** HHS announced a new distribution of $10 million from the $175 billion Provider Relief Fund (PRF) to support hospitals significantly impacted by COVID-19. During the course of two distributions, $22 billion has been allocated to high-impact areas, representing almost 12% of the entire $175 billion program.

According to data released by HHS, 47 Pennsylvania hospitals will receive $654,564,929 through this second round of hot spot money. Seventeen Pennsylvania hospitals had received $323,633,599 in the original hot spot distribution.

The second round of funding was based on a formula for hospitals with more than 161 COVID-19 admissions between January 1 and June 10, 2020, or one admission per day, or that experienced a disproportionate intensity of COVID-19 admissions (exceeding the average ratio of COVID-19 admissions/bed). All providers receiving PRF payments must comply with the reporting requirements described in the Terms and Conditions and specified in future directions issued by the secretary. Hospitals should continue to monitor updates posted at the HHS website.

**FDA Closing COVID-19 Hotline:** The Food and Drug Administration July 20 at 8 p.m. will close its COVID-19 hotline for questions related to COVID-19 diagnostic tests and device shortages, including personal protective equipment and respirators. Instead, FDA said the field should use this contact directory.

**NIH Panel Updates Remdesivir Treatment Guidelines:** In situations where supplies are limited, the National Institutes of Health’s COVID-19 Treatment Guidelines Panel recommended prioritizing remdesivir
for use in hospitalized patients with COVID-19 who require supplemental oxygen but are not mechanically ventilated or on extracorporeal membrane oxygenation. The panel expects to release additional updates to its recommendations for use of remdesivir soon.

**FDA Posts List of Removed Diagnostic Test Laboratories:** The Food and Drug Administration added to its [FAQs](https://www.fda.gov) on testing for SARS-CoV-2 a list of laboratories that should no longer be used. FDA said these laboratories initially reported they had developed and validated COVID-19 tests; however, FDA determined significant problems with these tests and should not be used.

**IRS Issues FAQ on Taxation of Provider Relief Payments:** The Internal Revenue Service July 6 issued a [clarification](https://www.irs.gov) on the tax treatment of funds received from the Provider Relief Fund. According to the FAQs, if the recipient is a taxable provider, the payments are taxable. If the provider is tax-exempt, the payments are not subject to tax unless the payment is reimbursement to the provider for lost revenue from an unrelated trade or business.

Nearly 20 health care provider organizations, including the American Hospital Association, on June 25 urged Congress to enact legislation to clarify that relief funds provided through the Public Health and Social Services Emergency Fund and other programs as part of the nation's response to the COVID-19 pandemic are exempt from taxation, and that entities receiving them maintain the tax deductions attributable to these funds.

**FDA Adds Drug to Compounding Lists; Recalls Hand Sanitizers with Wood Alcohol:** The Food and Drug Administration last week added dexamethasone sodium phosphate to its lists for temporary compounding by outsourcing facilities and pharmacy compounders during the COVID-19 emergency. Drugs on these lists are intended to address shortages and increase access in the treatment of COVID-19 patients.

The FDA also last week announced voluntary recalls of two hand sanitizers due to the potential presence of methanol, also known as wood alcohol. Both [AAA Cosmética, S.A. de C.V.](https://www.aaa-cosmetica.com) and [4e Brands North America](https://www.4ebrands.com) said they have not received complaints about the products.

**NIH Says Experimental COVID-19 Vaccine Safe, Generates Immune Response:** The first human study evaluating an mRNA COVID-19 vaccine made by Moderna Inc. produced neutralizing antibodies in healthy adults, who generally tolerated the vaccine well, the National Institutes of Health reports. The 45 participants received 25-, 100- or 250-microgram injections of the vaccine. The trial expanded to 120 participants in April, including the first adults over age 55. A phase 2 trial is underway to evaluate 50- and 100-microgram doses of the vaccine in 600 healthy adults, with plans to begin a large phase 3 trial of a 100-microgram dose this month.

**IRS Extends Deadline for Hospitals to Complete Community Health Needs Assessments:** The IRS announced that it is expanding the July 15 extension of time for tax-exempt hospitals to meet their community health needs assessment obligations. “The due date for any CHNA due to be conducted and for any implementation strategy due to be adopted on or after April 1, 2020, and before December 31, 2020, is postponed to December 31, 2020," the agency said.

The American Hospital Association, Association of American Medical Colleges and Catholic Health Association of the United States urged the Department of the Treasury and IRS to recognize the
extraordinary circumstances of hospitals in responding to and meeting the needs of communities as they confront the COVID-19 pandemic, and to grant relief from the current deadlines.

FDA Issues EUAs for Stimulator Device and Ventilator: The Food and Drug Administration last week authorized emergency use for a non-invasive nerve stimulator at home or in health care settings to treat suspected COVID-19 patients experiencing worsened asthma-related shortness of breath and reduced airflow. The device from electroCore, Inc. is intended for use when other drug therapies are not tolerated or do not provide enough symptom relief. FDA also authorized as a ventilator a CPAP mask combined with a N95 from Circadiance.

Report Calls for Evidence-based Guidelines for Preparedness Practices: The Centers for Disease Control and Prevention should appoint an independent panel to develop evidence-based practice guidelines for public health emergency preparedness and response and identify evidence gaps for future research, according to a report released by the National Academies of Sciences, Engineering, and Medicine.

“Preparing for and responding to public health emergencies requires scientific evidence to save lives, prevent social and economic disruption, and uphold national security,” said Ned Calonge, chair of the committee that wrote the report. “In the midst of the COVID-19 pandemic, now is the time for the nation to take stock of how we can improve the quality of research that is conducted before, during, and after public health emergencies.”

While not prepared in response to the pandemic, the report reviews the evidence for four public health emergency preparedness and response practices: engaging and training community-based partners to improve outcomes for at-risk populations; activating a public health emergency operations center; communicating public health alerts and guidance; and implementing a quarantine to reduce or stop the spread of a contagious disease. The authors recommend engaging and training community-based partners serving at-risk populations; including electronic messaging channels as part of a multipronged approach to communicating public health alerts and guidance to technical audiences; and implementing a quarantine during an outbreak only after considering the disease’s characteristics and the expected benefits, harms and feasibility. The authors found insufficient evidence to determine whether the common and standard practice of activating a public health emergency operations center improves response.

Appeals Court Upholds Short-term Plans Rule
A three-judge panel of the U.S. Circuit Court of Appeals for the District of Columbia reached a 2-1 decision upholding the Trump Administration’s regulations to rescind restrictions on short-term limited duration plans finalized in 2016 under the Obama Administration.

Why this matters: The upheld 2018 final rules allow the plans, which do not need to comply with ACA market reforms such as preexisting condition protections, to be offered up to one year in duration, subject to state law. Federal flexibilities around renewal were also finalized in the 2018 rules. While short-term plans are often significantly more affordable than an ACA compliant plan, they provide less coverage and expose the member to higher out-of-pocket costs.

The majority appeared to agree with proponents of the rule in concluding the agencies acted reasonably in light of (1) sufficient agency discretion provided by Congress to define short-term limited duration insurance; and (2) soaring premium increases of comprehensive coverage to allow plans to offer a lower premium
option (albeit with the potential for higher total out-of-pocket costs for costly episodes of care), particularly for those who do not qualify for Medicaid or federal premium tax credits.

**What’s next?** The rule was challenged by the Association of Community Affiliated Plans which released a statement immediately after the ruling indicating plans to appeal the ruling for a review by the full panel of Circuit Court judges. Efforts to rescind the 2018 regulations through legislation or administration action is likely to occur under a Biden administration.

In April 2018, insurer trade associations submitted comments to the proposed rule setting forth a number of high-level recommendations, including, among other things:

- Limiting the duration of STLDI plans to six months;
- Not permitting renewals;
- Providing plain-language disclosures to consumers; and
- Reaffirming the right of states to regulate short-term plans in their markets more stringently than they are regulated under federal rules.

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**Court Sides with Administration on Site-Neutral Hospital Payments**

Last week, a federal appeals court ruled that Medicare may cut payments to hospital clinics for basic services typically provided at lower costs at independent physician offices, upholding a key piece of the Trump Administration’s health care cost agenda.

The so-called site-neutral policy has been a priority of the Centers for Medicare & Medicaid Services (CMS) Administrator Seema Verma, who calls it an effective weapon against hospital consolidation and a boost for competition that can lower the nation’s high health care costs.

A three-judge panel of the Washington, D.C. Court of Appeals ruled that HHS had the legal authority to unilaterally cut payments to hospital clinics. The policy took effect during January 2019 before a district court judge blocked it last summer. The unanimous ruling repeatedly dismissed hospitals’ claims that the federal government violated Congressional intent in cutting Medicare’s rates to their outpatient clinics.

The Trump Administration continued the policy for 2020, even after the district court froze the 2019 pay cuts. Hospitals also sued to block the 2020 reductions, although this decision likely means Medicare can move ahead with implementing them.

The site-neutral policy is popular among many health care economists who said hospitals had previously been incentivized to buy up physician practices to net higher payment rates. Hospitals say the higher payments are justified because these clinics have higher costs.

During 2019, hospitals faced a $380 million cut in Medicare payments as the policy was phased in. During 2020, the policy would reduce reimbursement by an estimated $760 million.

The policy has been fiercely contested by hospitals, which say it could force them to make difficult decisions about whether to reduce services in response to the lowered payment rate.

The American Hospital Association has not yet determined if hospitals will appeal the site-neutral decision.
Legislation Targeting the Reopening of Counties Continues to Garner Attention

The House of Representatives this week continued to press for changes in the way Governor Tom Wolf is addressing the reopening of the state during the COVID-19 crisis. According to Administration officials, the spike in coronavirus cases has warranted adjustments, including how restaurants operate and the availability of alcohol. Legislation considered this week includes the following:

- **House Bill 2541** – Allows counties to develop and implement a countywide reopening plans for businesses that were subject to closure by the Governor’s Business Closure Order. House Republicans believe this proposal provides counties with more flexibility to modify their reopening decisions over time if they find them to be unsafe. Democrats, however, view the measure as another attempt to limit the Governor’s ability to protect state residents. House Bill 2541 passed by a 114-87 margin. It has been sent to the Senate for further consideration.

- **House Bill 2549** – Permits a county to pass a resolution to move to the Green Phase of reopening after being in the Yellow Phase of reopening for at least 21 days. The bill also allows a county that’s been in the Green Phase for 14 days to transfer to the Green Plus Phase, if the county meets CDC requirements. The measure was passed by a vote of 116-85. The bill has been sent to the Senate for further consideration.

Grant Funding Available for Employee Hazard Pay during COVID-19

Governor Tom Wolf announced the availability of $50 million in grant funding to help employers provide hazard pay to employees in life-sustaining occupations during the COVID-19 pandemic.

Created through the federal Coronavirus Aid, Relief, and Economic Security (CARES) Act, the [COVID-19 PA Hazard Pay Grant](#) program is available to employers offering hazard pay during the eligible program period and will be administered by the Department of Community and Economic Development (DCED). Hazard pay means additional pay for performing hazardous duty or work involving physical hardship, in each case that is related to COVID-19.

**Eligible Pennsylvania-based industries include:**

- Hospitals;
- Health care and social assistance;
- Ambulatory health care services;
- Nursing and residential care facilities;
- Transit and ground passenger transportation;
Food manufacturing;
Food retail facilities;
Janitorial services to buildings and dwellings; and
Security services for eligible industries listed above and commercial industries that were not closed as a result of the governor’s business closure order.

Grant funds may be used for hazard pay for direct, full-time, and part-time employees earning less than $20/hour (excluding fringe benefits and overtime). Applicants may apply for up to $1,200 per eligible full-time equivalent employee. The hazard pay must be paid to the eligible employee during the ten-week period of August 16 through October 24, 2020, as a $3/hour hazard pay increase to their regular pay rate.

Employers may apply for a grant to provide hazard pay for up to 500 eligible full-time equivalent employees per location ($600,000 maximum grant per location). No employer may receive more than $3,000,000 of the funding under the COVID-19 Hazard Pay Grant Program.

Eligible applicants may apply for grants using the online Electronic Single Application for Assistance form from July 16 to July 31, 2020.

For more information, call (717) 787-6245 or email DCED.

Why this matters: In order to make certain that hospitals are able to continue to provide treatments, front-line health care personnel are able to provide care and patients are able access health care services, government affairs has been urging both federal and state lawmakers to allocate additional resources for the health care system. Specifically, support for child care, housing, transportation and education benefits for hospital workers; bonus pay for hospital workers; and to establish a compensation fund for COVID-19 health care workers and their families.

DHS Announces Regional Response Health Collaborative Program Participants

Last week, the Pennsylvania Department of Human Services (DHS) announced selected health systems and academic medical centers for the new Regional Response Health Collaborative Program (RRHCP). The RRHCP replaces the Education Support and Clinical Coaching Program in providing operational, clinical, and administrative support for long-term care facilities as they work to protect their residents and staff from COVID-19.

Applicants selected for the RRHCP, regions they will serve, and grant amounts include:

- Thomas Jefferson University and the University of Pennsylvania, Southeast Pennsylvania, $65.8 million;
- Geisinger Clinic and Lehigh Valley Hospital, Northeast Pennsylvania, $24 million;
- The Pennsylvania State University, Southcentral Pennsylvania, $22.9 million;
- Geisinger Clinic, Northcentral Pennsylvania, $9.8 million;
- UPMC Community Provider Services, Southwest Pennsylvania, $38.9 million; and
- LECOM Health and UPMC Community Provider Services, Northwest Pennsylvania, $13.6 million.

These organizations may choose to work with other health networks and not-for-profits to meet the needs of long-term care facilities in the region they will serve.
**Why this matters:** AHN is partnering with both UPMC and LECOM in the Regional Response Health Collaborative Program to serve the Southwest and Northwest regions respectively.

This new network will continue efforts that began by supporting long-term care facilities across Pennsylvania as they respond to COVID-19, through sharing best practices in infection control, assisting with contact tracing efforts, and providing on-site and virtual clinical consultations.

RRHCP partners also will assist with baseline universal testing required under the Department of Health’s expanded testing order issued during the end of June. This testing also will cover asymptomatic staff and residents.

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**DOH Updates Guidance for Return to Work for Health Care Personnel with Confirmed or Suspected COVID-19**

The Pennsylvania Department of Health (DOH) released [PAHAN-516](https://www.health.pa.gov) and [PAHAN-517](https://www.health.pa.gov) through its Health Alert Network (HAN). These HANs reflect updated guidance published by the Centers for Disease Control and Prevention on July 17, 2020.

PAHAN-516 provides updated information pertaining to when and how health care personnel who have had confirmed or suspected COVID-19 can return to work. *Except for rare situations, a test-based strategy is no longer recommended.*

Other changes include extending exclusion from work to 20 days after symptom onset for severe to critical illness or those severely immunocompromised, other symptom-based criteria modifications, and return to work restrictions including during crisis capacity prioritization. Information in this HAN replaces PAHAN-501.

PAHAN-517 provides updated guidance for discontinuing transmission-based precautions for confirmed or suspected COVID-19 patients. *This update changes precaution discontinuation from a test-based to a symptom-based strategy for the majority of patients, while offering guidance about when to continue a test-based strategy for rare situations.* Patients who have severe to critical illness or those that are severely immunocompromised, are recommended an extended precaution period of 20 days after symptom onset, or 20 days after initial positive SARS-CoV-2 diagnostic test for asymptomatic severely immunocompromised patients.

PAHAN-517 also contains additional symptom-based criteria and modifications, including discharge from the health care facility guidance and the conditions that apply to declare a long-term care facility or unit that housed COVID-19 positive residents to be unaffected by COVID-19. Information in this HAN replaces PAHAN-502.

All Pennsylvania DOH HAN notifications can be found at the [DOH website](https://www.health.pa.gov). To sign up for notifications, visit the [PA HAN website](https://www.health.pa.gov).

The Centers for Disease Control and Prevention continues to closely monitor COVID-19 and update its guidance as new information is known in order to allow healthcare providers to make appropriate decisions about infection control and management of patients.

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**State Issues**
West Virginia
Legislative

West Virginia Delegates Call for Special Session to Oversee COVID-19 Response, Governor Justice Objects
West Virginia delegates are calling for a special legislative session to oversee parts of the state’s COVID-19 response. Part of the review would include the allocation of $1.25 billion in federal CARES Act funding. The calls occurred during a virtual town hall with U.S. Senator Joe Manchin (D-WV), where more than 60 delegates of both parties, plus one independent, signed requests to convene in a special legislative session. While this number represents enough for a supermajority in the House of Delegates, a special session would also require the participation of the state Senate, which has not been calling for such a session.

Meanwhile, Governor Jim Justice has expressed opposition to the request, believing the assembly discussion would be purely political and a waste of taxpayer dollars. Delegates, which want to spend funds to help West Virginia’s businesses, object to Governor Justice’s proposal to spend about half the money — $687 million over the next two years — to bolster the unemployment insurance fund run through Workforce West Virginia.

Regulatory

Governor Justice Issues New COVID-19 Guidance for State Residents
With the number of coronavirus cases rising, Governor Jim Justice issued new Executive Orders addressing the following:

- Reducing social gatherings to 25. This does not apply to any activity, business, or entity deemed essential, including weddings, religious services, group meetings, conferences or other special events held for essential businesses and operations;
- Fairs, festivals, carnivals, indoor/outdoor concerts or similar events are prohibited; and
- Statewide wearing of face coverings in public places when social distancing cannot be maintained remains in effect.
Interested in reviewing a copy of a bill(s)? Access the following web sites:

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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