Federal Issues
Legislative

Senate GOP Offers Slimmed Down COVID-19 Package
Republicans in the U.S. Senate have released a revised coronavirus stimulus package as gridlock in Congress continues to stymie negotiations over additional aid.

Why this matters: The move comes as the House interrupted its August recess to vote on standalone legislation to provide $25 billion for the U.S. Postal Service amid concerns about ensuring sufficient resources to handle mail-in ballots ahead of the November elections.

The new GOP COVID proposal includes:
- $300 in weekly federal unemployment insurance;
- Paycheck Protection Program (PPP) extension;
- Liability protections during the pandemic; and
- Additional funding for the postal service, testing, vaccines, and schools.

Next steps: With the Republican National Convention underway this week and Labor Day soon to follow, agreement on a fourth COVID-19 relief bill seems unlikely before mid-September. It is possible an...
agreement may not be reached before the November election.

Federal Issues
Regulatory

Appeals Court Rules ACA Subsidies are Owed to Plans, with Offsets
A three-judge panel of the Court of Appeals for the Federal Circuit issued two decisions concluding that insurers are entitled to unpaid cost-sharing reductions (CSRs), an Affordable Care Act (ACA)-created health insurance subsidy to reduce the out-of-pocket expenses for eligible enrollees.

Background
- In October 2017, the Trump Administration released a legal opinion concluding the CSRs were never appropriated by Congress and therefore must be terminated immediately.
- The decision resulted in substantial unpaid subsidies, used to lower out-of-pocket costs for low-income Exchange enrollees, for the remainder of 2017.
- In 2018 and each subsequent year, insurers and state regulators have responded by allowing insurers to load the unpaid subsidies into premium rates, boosting the value of premium tax credits and holding enrollees harmless, even resulting in $0 premium plans for many consumers.

The U.S. Supreme Court’s decision this year over unpaid funds through another ACA program (risk corridors) influenced the appeals court’s decisions to find insurers were entitled to unpaid CSRs for 2017. However, the amount that insurers would have been paid in 2018 must be reduced by the amount they received in advanced payments of the premium tax credits due to premium loading so as not to result in, in the court’s view, a double recovery. Calculating the actual amounts owed in damages will be determined in lower court proceedings. Further, the decision could trigger new guidance from federal and state insurance regulators on the practice of premium loading going forward.

Court Orders HHS to Halt Parts of ACA Nondiscrimination Rule Implementation
A few changes made in a recently revised final rule that rolled back the scope of nondiscrimination protections related to gender identity, sexual orientation and pregnancy status in health programs and activities were vacated last Monday, one day before the rule was to take effect.

Background
• Section 1557 of the Affordable Care Act “prohibits discrimination based on race, color, national origin, sex, age or disability in certain health programs or activities.”
• In May of 2016, a rule was issued implementing section 1557; interpreting the ban on sex discrimination to include protections for individuals regardless of gender identity, sexual orientation, and pregnancy status. However, certain provisions of this 2016 rule related to the definition of sex discrimination were challenged in court.
• The Trump Administration issued a final rule in June, reversing some of the 2016 rulemaking.

The revised final rule issued in June:
• Eliminated gender identity, sexual orientation, and pregnancy status as categories protected under the term “sex”;
• Eliminated requirements for meaningful language access for people with limited-English proficiency; and
• Limited the scope of the rule to programs that receive federal financial assistance.

Why this matters:
• The final rule has been challenged (in whole and in part) in multiple federal courts, but a district court judge for the Eastern District of New York was the first to reach a ruling.
• The judge concluded that the Department of Health and Human Services’ Office of Civil Rights improperly issued the final rule immediately before the U.S. Supreme Court rendered the Bostock decision, finding Title VII of the Civil Rights Act prohibits employment discrimination based on sexual orientation or gender identity.
• As a result, the definitions of “on the basis of sex,” “gender identity,” and “sex stereotyping” will remain in effect.
• The decision is narrowly tied to reinstating some aspects of the 2016 rule tied to sex discrimination. It does not affect how other courts interpret the statute itself in light of Bostock nor other parts of the 2020 final rule, including the narrowed scope of entities and health programs subject to the rule as well as language access standards.

Insurer & Hospital perspective: AHIP President and CEO Matt Eyles released a statement earlier this year, stating that “[AHIP] resolutely disagrees with any attempt to remove protections in federal law that prohibit discrimination based on gender identity, sex stereotyping, and pregnancy status. We also firmly believe that non-English speakers should have ready access to health information. Discrimination is wrong – period.” AHIP previously submitted a comment letter on the proposed rule last August.

The American Hospital Association had strongly urged HHS not to finalize their proposal, expressing concerns that "narrowing the current regulation's protections against discrimination based on sex, including gender identity, sexual orientation, and sex stereotypes, could have an adverse impact on access to care and the health of individuals. The AHA also submitted a comment letter on the rule in August 2019.

CMS Releases Risk Adjustment Data Validation Summary Report for 2018
The Centers for Medicare & Medicaid Services released an annual summary report detailing the impact of risk adjustment data validation (RADV) adjustments to ACA risk adjustment payment transfers for the 2018 benefit year.

**Why this matters:** This summary report includes insurer-specific adjustments to risk adjustment transfer results, based on RADV results, and will generally be used to adjust 2019 benefit year plan liability risk scores, resulting in adjustments to 2019 benefit year risk adjustment transfer amounts. CMS will collect and distribute 2018 benefit year RADV adjustments to 2019 benefit year risk adjustment transfers in the 2022 calendar year, as provided for under the revised timeline included in the 2020 final payment notice.

**Key findings from the report include the following:**
- 2018 benefit year RADV results in 59 of 146 state market risk pools having 2019 benefit year risk scores and transfers adjusted due to outlier issuers;
- For the 2019 benefit year, RADV adjustments as a percent of premiums decreased on average across all three market risk pools; and
- The 2018 benefit year RADV adjustments reflect a higher proportion of issuers receiving a RADV adjustment payment than in 2017 benefit year RADV adjustments due to the higher proportion of negative error rate outliers in 2018 benefit year RADV.

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**AHA Expresses ‘Profound Concern’ About Drug Companies’ Actions to Undermine the 340B Program**

The American Hospital Association sent letters to the heads of U.S. operations for five large drug companies — Merck, Eli Lilly, Sanofi, Novartis, and AstraZeneca — expressing “profound concern” over actions they are taking to limit the distribution of certain 340B drugs to hospitals and health systems and asking them to “cease this conduct immediately.”

These actions range from limiting the distribution of certain 340B drugs to demanding, on short notice, superfluous, detailed reporting on 340B drugs distributed through hospitals’ contract pharmacies.

The AHA said “for a drug company to jeopardize hospitals’ ability to care for patients who are already under severe economic, emotional, and health-related strain during a public health crisis is unconscionable.” The AHA urged the drug companies to stop this conduct and work to ensure that 340B drugs are available and accessible to vulnerable communities and populations.

**Why this matters:** These actions by drug companies are attempting to compel hospitals to divert critical resources away from the pandemic at a time when hospitals are in the midst of their response to the COVID-19 public health emergency — the very situation, which has further demonstrated the fractured, inadequate state of the prescription drug supply chain.

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**DEA Publishes Rulemaking Notice for Reporting Controlled Substance Theft and Losses**

On July 29, 2020, the Drug Enforcement Administration (DEA) published a notice of proposed rulemaking for reporting of thefts or significant losses of controlled substances.

Specifically, DEA proposes two changes to the reporting process:
- **Registrants must submit the DEA Form 106 electronically.** As noted in the proposed rule, 99.5% of theft/loss forms are currently submitted electronically. This change simply reflects what is already
being done by the regulated industry and should elicit few, if any, comments objecting to the change.

- **The DEA Form 106 must be filed within 15 calendar days.** The proposed rulemaking would require facilities to electronically file DEA Form 106 within 15 calendar days.

As the DEA reminds us, current regulations are silent on the timing for filing Form 106 after submission of the initial notification. DEA’s historical guidance to registrants has been that if Form 106 could not be filed within 60 days (a very rare occurrence), the registrant should provide the local office with an update of the investigation. While creating a deadline for filing Form 106 is appropriate, the proposed period may create more issues than it solves. While some investigations can be completed within 15 calendar days, many cannot. Filing Form 106 in 15 days and before the full investigation is completed will require the registrant to file an amended Form 106 at some later time at the conclusion of the investigation. If the goal is to get timely, complete, and accurate information regarding the circumstances of a theft or loss, DEA should consider giving registrants 30 or 45 days to complete investigations, with the opportunity to extend the deadline, with DEA’s permission, when warranted.

Comments on the proposed rule are due no later than September 28, 2020.

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

**FDA Authorizes COVID-19 Convalescent Plasma for Hospitalized Patients:** The Food and Drug Administration issued an emergency use authorization for investigational convalescent plasma to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients.

COVID-19 convalescent plasma is human plasma collected by FDA-registered blood establishments from individuals whose plasma contains SARS-CoV-2 antibodies. Based on the available scientific evidence, FDA said it was reasonable to believe the treatment may reduce COVID-19 severity or length of illness in some hospitalized patients, and that the known and potential benefits outweigh the known and potential risks. Information derived from ongoing clinical trials “will continue to inform this risk benefit assessment,” the agency said. For more on the EUA, see the fact sheets for [health care providers](#) and [patients](#).

In related news, the Department of Health and Human Services’ Office for Civil Rights issued amended guidance on how the Health Insurance Portability and Accountability Act Privacy Rule permits covered health care providers and health plans to contact their patients and beneficiaries who have recovered from COVID-19 to inform them about how they can donate convalescent plasma.

According to OCR, the updated guidance clarifies how HIPAA permits health plans to contact their beneficiaries about plasma donation opportunities. The guidance also emphasizes that, without individuals’ authorization, the providers and health plans cannot receive any payment from or on behalf of a plasma donation center in exchange for such communications with recovered individuals, OCR said.

**HHS Clarifies Laboratory Developed Tests Do Not Require FDA Approval or Authorization:** In an effort to reduce regulatory burden, the Food and Drug Administration will not require developers to submit a premarket approval application, premarket notification or emergency use authorization for laboratory developed tests, the Department of Health and Human Services announced last week.

Laboratories opting to use these tests would not be eligible for Public Readiness and Emergency Preparedness Act coverage and would remain subject to regulation by the Centers for Medicare & Medicaid
Services under the Clinical Laboratory Improvement Amendments of 1988 and its implementing regulations, HHS said. LDT developers may voluntarily apply for approval, clearance or an EUA, and FDA will adjudicate those submissions.

LDTs are developed, validated, and performed by individual laboratories, including hospital laboratories, when commercial diagnostic tests do not exist or meet clinical needs. Hospitals have urged the agency not to regulate LDTs as medical devices, which would reduce patient access to many critical tests and hinder technological and clinical innovation.

**FDA Authorizes Novel Point-of-Care Antigen Test:** The Food and Drug Administration authorized emergency use of a rapid point-of-care antigen test to detect SARS-CoV-2 directly from nasal swab specimens.

Laboratories certified under the Clinical Laboratory Improvement Amendment to perform moderate, high or waived complexity tests and health care providers with a CLIA certificate of waiver, compliance or accreditation may use the test, made by LumiraDx UK Ltd.

Assistant Secretary for Health Admiral Brett Giroir, M.D., said the novel “low cost” test “will significantly contribute to our scaling up and expanding testing platforms for SARS-CoV-2. This technology has built-in digital connectivity, almost everything we hope for in new testing platforms coming to market. Furthermore, its flexibility to perform diagnostic assays to detect indicators of various diseases, including inflammatory markers, could be transformative in providing improved access to quality health care.”

**CDC Releases 2020-2021 Flu Vaccination Recommendations:** The Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices released its recommendations for the 2020-2021 flu season, which continue to advise yearly flu vaccinations for all people aged 6 months and older. It expects this season’s flu vaccines to include inactivated, recombinant, and live attenuated vaccines, including two new vaccines expected to produce a better immune response in people aged 65 years and older.

“Because the viruses that cause flu and COVID-19 might spread at the same time this fall and winter, getting a flu vaccine is particularly important as a way to reduce the amount of flu disease and symptoms that may be confused with COVID-19, and to reduce stress on the U.S. healthcare system,” CDC said.

**CMS Resumes Routine Inspections of All Providers and Suppliers:** The Centers for Medicare & Medicaid Services announced it will resume routine inspections of all Medicare- and Medicaid-certified providers and suppliers that were previously suspended as part of its response to the COVID-19 pandemic.

In the guidance, CMS directed the resumption of onsite revisit surveys, non-immediate jeopardy complaint surveys and annual recertification surveys as soon as resources are available. The agency also provided guidance on resolving enforcement cases that were previously on hold because of survey prioritization changes, while temporarily expanding the desk review policy to include all noncompliance reviews except for immediate-jeopardy citations that have not been removed.

CMS has expanded the desk review policy for all facilities. State surveyors can perform desk review on all open surveys cited at any level of noncompliance. Additionally, providers will be granted ten calendar days to submit a plan of correction for surveys that ended prior to June 1, 2020.
HHS Expands Access to Childhood Vaccines During Pandemic: The Department of Health and Human Services amended the declaration under the Public Readiness and Emergency Preparedness Act to authorize state-licensed pharmacists and pharmacy interns under their supervision to order and administer vaccines to children, subject to certain requirements.

"Today's action means easier access to lifesaving vaccines for our children, as we seek to ensure immunization rates remain high during the COVID-19 pandemic," said HHS Secretary Alex Azar.

The Centers for Disease Control and Prevention in May reported a notable drop in routine childhood vaccines ordered and administered through the federal Vaccines for Children program during the public health emergency.

FDA Releases Tool to Help Facilities Select Respirators: The Food and Drug Administration released a resource to help U.S. health care providers select respirators for their health care facility. It includes a flowchart and information to help identify the emergency use authorization for specific types of respirators and the performance factors to consider for each type.

NIOSH Releases Assessment of Non-NIOSH N95 Respirators: The National Institute for Occupational Safety and Health released a report summarizing the particulate filtration efficiency of non-NIOSH-approved N95 respirators made in other countries and authorized for emergency use during the COVID-19 public health emergency.

The agency conducted 105 assessments of 102 models made by 87 manufacturers at the request of states, health care providers, non-health care employers, first responders, and others. About 40% of the respirators tested below 95% particulate filtration efficiency for all units tested, 33% above 95% for all units tested, and 27% had mixed results.

Based in part on these results, the Food and Drug Administration on May 7 removed 57 respirators from its international emergency use authorization list, the report notes.

American Hospital Association Recommends Action on Telehealth in Response to President’s Executive Order: The American Hospital Association urged President Trump and the Department of Health and Human Services to continue to act on behalf of hospitals and health systems by further expanding telehealth flexibilities. In a letter to the president, AHA recommended steps that support patients’ continued access to telehealth services after the expiration of current COVID-19 public health emergency declarations.

CDC Reports Examine COVID-19 Hotspots, Racial and Ethnic Disparities: One in four U.S. counties, or 818, were COVID-19 hotspots for at least one day in the period between March 8 and July 15, representing 80% of the U.S. population, according to a report released Friday by the Centers for Disease Control and Prevention. A second report found that of the 205 hotspot counties identified nationwide in June, only 79 counties reported the patient’s race for more than 50% of cases, and in 96% of those counties, racial and ethnic disparities were noted. Additionally, CDC released a report on racial and ethnic disparities in COVID-19 workplace outbreaks in Utah. Hispanic and other non-white workers accounted for 73% of the 1,389 COVID-19 cases associated with workplace infections in Utah between March 6 and June 5. The outbreaks were primarily in manufacturing, construction, and wholesale trade.
**CDC Updates Numerous Guidance Related to COVID-19:** The Centers for Disease Control and Prevention recently updated its guidance for determining when health care personnel with confirmed or suspected COVID-19 may return to work. Among the changes, for health care personnel with severe to critical illness or who are severely immunocompromised, the recommended duration for work exclusion is changed to at least 10 days and up to 20 days after symptom onset. Further, the guidance includes a recommendation to consider consultation with infection control experts; adds an example applying disease severity in determining duration before return to work; and adds hematopoietic stem cell or solid organ transplant to severely immunocompromised conditions. CDC also makes similar updates to its guidance on when health care facilities may discontinue transmission-based precautions or discharge patients infected with SARS-CoV-2. The agency said the changes more closely align with its recent decision memo on duration of isolation and precautions for adults with COVID-19.

**FDA Alerts Laboratories and Providers to Risk of False Results with COVID-19 Test Kit:** A test kit made by Thermo Fisher Scientific to detect COVID-19 from respiratory specimens may produce false positive results, the Food and Drug Administration warned.

The agency recommends that clinical laboratories and health care providers using the TaqPath COVID-19 Combo Kit promptly implement updates to the software and use instructions, among other actions.

The FDA in March authorized the test for emergency use by U.S. laboratories certified to perform moderate and high complexity tests under the Clinical Laboratory Improvement Amendments. The agency is working with Thermo Fisher Scientific and public health partners to resolve the problem and plans to update the public as information becomes available.

**CMS Issues New Requirement for DRG Add-on:** The Centers for Medicare & Medicaid Services updated its guidance related to the 20% inpatient prospective payment system diagnosis-related group rate add-on for patients diagnosed with COVID-19.

For inpatient admissions occurring on or after September 1, 2020, claims eligible for the 20% add-on will be required to have a positive COVID-19 laboratory test documented in patients’ medical records.

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**State Issues**

**Pennsylvania**

**Regulatory**

**Governor Wolf Extends Opioid Disaster Declaration, Naloxone Standing Order Updated**

Governor Tom Wolf has extended his opioid declaration to continue the fight against the growing opioid and heroin epidemic. This notice represents the 11th renewal of the declaration and allows the state to adjust regulations and procedures in order to expedite support and treatment to affected individuals. “In the midst of the COVID-19 pandemic, the commonwealth’s Opioid Command Center continues its work to fight another health crisis – the opioid epidemic,” Gov. Wolf said.

The declaration, initially issued January 2018, allows for the redirection and reorganization of commonwealth resources to better align programs from multiple agencies to help mitigate the crisis, its causes and its effects.
On August 18, Secretary of Health Dr. Rachel Levine signed an updated naloxone standing order permitting community-based organizations to provide naloxone by mail to assist organizations with distributing naloxone to Pennsylvanians in-need while reducing the risk of COVID-19 transmission. State residents may continue to obtain naloxone, which is a life-saving medication that can reverse the effects of an opioid overdose, via a pharmacy under a previous standing order issued by Dr. Levine.

Governor Wolf and Dr. Levine highlighted some of the successes related to the opioid and heroin epidemic, including but not limited to the following:

- The Prescription Drug Monitoring Program has reduced opioid prescriptions by 34% and has virtually eliminated doctor shopping;
- The number of people receiving high dosages of opioids (defined as greater than 90 morphine milligram equivalents per day) has dropped 53% since the PDMP launched in August 2016;
- 11 Pennsylvania Coordinated Medication Assisted Treatment (PacMAT) programs are serving as part of a hub-and-spoke model to provide evidence-based treatment to people where they live, with just under $26 million dedicated into the centers;
- More than 45 Centers of Excellence, administered by the Department of Human Services, provide coordinated, evidence-based treatment to people with an opioid use disorder covered by Medicaid. The COEs have treated more than 32,500 people since first launching in 2016;
- Education has been provided to more than 6,600 prescribers through either online or face-to-face education;
- The Get Help Now Hotline received close to 38,700 calls, with nearly half of all callers connected directly to a treatment provider;
- Education and training on opioids have been provided to schools. Future plans are in place to make opioid education a standard component of their school-based training;
- The coordination with seven major commercial providers has expand access to naloxone and mental health care, while also working to make it more affordable; and
- EMS have administered more than 40,600 doses of naloxone and more than 10,000 doses were made available to members of the public during the state’s naloxone distribution last year.

For more information on Pennsylvania’s response to the opioid crisis visit www.pa.gov/opioids.
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/.
If you have any questions about a DE, PA, WV or congressional bill, contact the Government Affairs Department at (717).302.3978.

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