Federal Issues
Legislative

Capitol Hill Slowly Resumes Business Amid Outbreak
On May 4, Senate lawmakers returned to Capitol Hill and officially resumed their spring work period with Republicans moving quickly to resume consideration of judicial and executive branch nominations and begin COVID-19 related hearings. The timing of return for the House is more complicated, as there are more than four times as many House Members as Senators, who would have to work in approximately the same amount of space.

HELP Committee Considers ‘Shark Tank’ Proposal
On Thursday, the Senate HELP Committee held a hearing on a joint proposal by Chairman Lamar Alexander (R-TN) and Senator Roy Blunt (R-MO) to create a “Shark Tank” initiative among federal agencies to expedite development of COVID-19 testing technologies and products.

- Alexander emphasized that, to conduct widespread testing at nursing homes, prisons, universities and businesses, and potentially multiple times, “millions” of tests will be needed

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and that this demand exceeds our current testing capacity. Thus, there is a **vital need for new testing technologies** as the country enters a new phase of the COVID-19 health crisis.

- Ranking Member Patty Murray (D-WA) used her opening statement to **criticize the president for the lack of a national testing strategy** and that while she appreciated the interest in a “Shark Tank” initiative, she said “the fight against this virus is reality; it is not reality television.”

- Dr. Gary Disbrow, acting director of the Biomedical Advanced Research and Development Authority (BARDA) **noted** that the agency created a **portal where healthcare companies could submit emerging, promising technologies** for review by BARDA and potential federal funding. More than 2,500 applications have been submitted through the portal as of May 1, and BARDA has held over 250 meetings with companies that applied.

- Similarly, Dr. Francis Collins, director of the NIH, **described** a public-private partnership known as ACTIV — Accelerating COVID-19 Therapeutic Interventions and Vaccines. This partnership, led by NIH, has helped the COVID-19 response by **accelerating and coordinating scientific review** of approximately 170 therapeutic compounds and more than 50 vaccine candidates.

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Senate Democrats Call for National Testing Strategy
On Tuesday, 42 Democratic senators, including Majority Leader Chuck Schumer (D-NY) and Sen Patty Murray, sent a letter to President Trump urging him to release a national testing strategy to “quickly scale and optimize COVID-19 testing,” noting that it is required by the recent coronavirus aid legislation. The letter presses for details on the administration’s plan.

HELP Committee Announces COVID-19 “Back To Work” Hearing
The Senate HELP Committee announced that it will hold a full committee hearing Tuesday on “COVID-19: Safely Getting Back to Work and Back to School.” The virtual hearing will include Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, and other members of the White House’s coronavirus task force.

Congress Urged to Shield Health Care Facilities and Providers from COVID-19 Liability
The American Hospital Association and other national hospital organizations asked congressional leaders to include in the next COVID-19 legislative package provisions to shield from unwarranted liability the health care facilities and providers treating patients during the pandemic.

In addition to AHA, the letter was signed by America’s Essential Hospitals, the Association of American Medical Colleges, Catholic Health Association of the United States, Children’s Hospital Association, Federation of American Hospitals, National Association for Behavioral Healthcare, Premier health care alliance and Vizient Inc.

Why this matters: A number of states have either issued Executive Orders or enacted legislation to support their health care facilities and professionals. These measures are designed to shield front-line providers from the legal exposure that results from actions and decisions undertaken in responding to an unprecedented public health emergency. However, not every state has taken action, and a federal legislative approach is necessary to ensure a consistent level of protection is available for every facility and provider.

Pennsylvania is only one of a few states that has not enacted liability reforms for health care facilities during the COVID-19 pandemic. An Executive Order released last week by Governor Wolf provided limited liability protections to health care providers and did not afford any protection to health care facilities including hospitals.

U.S. Supreme Court Activity
Developments occurred last week in two Affordable Care Act (ACA) related cases pending before the U.S. Supreme Court.

Texas v. U.S. (challenges the constitutionality of the ACA)
Opening briefs were filed on May 6 by the California-led group states and the U.S. House of Representatives in their effort to overturn a district court decision invalidating the ACA following the zeroing out of the individual mandate penalty.
The parties raise arguments similar to those made in the district court proceedings and on appeal. In particular, that the TX-led states and individual plaintiffs challenging the law lack standing to file suit, the individual mandate remains constitutional despite Congressional action reducing the penalty for failing to have insurance $0, and in the event the mandate as amended is found to be unconstitutional, the remainder of the ACA remains valid.

Also on Wednesday, the Administration indicated it would continue to support invalidating the ACA in its entirety, following reports that Attorney General Barr had urged the Administration to consider adjusting its position in the case. Briefing in the case is expected to conclude in mid-August and the Supreme Court is expected to hear oral arguments in the fall. A decision in the case is expected next year.

**Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania and Trump v. Pennsylvania**

(challenging the expansion of a religious exemption to providing contraceptive coverage)

The Supreme Court heard oral arguments by telephone conference on May 6 regarding the ACA’s “birth control mandate,” in *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania and Trump v. Pennsylvania*.

- These consolidated cases involve a challenge by the states of Pennsylvania and New Jersey to regulations expanding an exemption from the mandate to health plans sponsored by many types of non-governmental employers, including non-profit and for-profit corporations, churches, and institutions of higher education.
- The states argued that they would have to shoulder much of the cost of providing contraceptives to women who lost coverage under the rules.
- The birth control mandate has been the subject of long-standing litigation. In 2017, the administration issued rules expanding the exemption allowing employers with religious or moral objections to opt out of providing coverage without any notice to the government.
- A decision could come as early as June; for now, the Obama-era accommodations process remains in place.

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**Federal Issues**

**Regulatory**

**CMS Publishes Final Payment Notice and Rate Filing Deadlines for ACA Issuers**

The Centers for Medicare & Medicaid Services (CMS) issued the final 2021 Notice of Benefit and Payment Parameters and related guidance for qualified health plan (QHP) issuers for the 2021 plan year, including flexibility in rate filing deadlines to provide additional time for issuers to incorporate COVID-related assumptions in 2021 rates.

The 2021 Payment Notice addresses a number of issues, including:

- **Prescription Drug Coupons.** The Notice finalizes a proposed change to cost-sharing limit requirements to remove references to drugs with a generic equivalent. It also clarifies health plans and issuers have the flexibility to determine whether to include coupon amounts and other drug manufacturer direct assistance from the annual limitation on cost sharing, regardless of whether a generic equivalent is available.
• **Automatic Reenrollment.** The Notice does not finalize any changes related to the automatic re-enrollment process. CMS notes commenters unanimously supported retaining the automatic re-enrollment processes and believes existing Exchange safeguards have mitigated the risk of inappropriate APTC payments.

• **Value-based Insurance Design (VBID).** It finalizes the provisions as proposed, with the final rule adding specificity around how issuers could voluntarily incorporate VBID principles into their QHPs. CMS declined to establish a method for identifying value-based plans on HealthCare.gov and will not require the development of a standardized VBID option for QHPs. CMS will also consider ways for standalone dental plans to adopt VBID principles.

• **User Fees.** The Notice maintains user fee levels for the 2021 benefit year of 3% of premiums for FFE issuers and 2.5% of premiums for issuers in State-based Exchanges on the Federal platform (SBE-FPs), consistent with 2020 user fees.

• **Maximum Annual Limitation on Cost-Sharing.** It finalizes 2021 maximum annual limitation on cost sharing $8,550 for self-only coverage and $17,100 for coverage other than self-only coverage, an approximate 4.9 percent increase above the 2020 limits.

• **Risk Adjustment.** It finalizes proposals to recalibrate the risk adjustment model and incorporates related updates to other elements of the model, including changes to the hierarchical condition categories (HCC). The recalibration is aimed at incorporating the most recent years’ claims experience available while the updates to the HCCs are intended to reflect more recent treatment patterns and costs. Additionally, the final notice moves forward with pricing adjustment for RXC for hepatitis C drugs and incorporating PrEP as a preventive service in the risk adjustment model.

• **Risk Adjustment Data Validation (RADV).** The Notice finalizes the policy that CMS will not consider issuers with fewer than 30 HCCs in an HCC failure rate group to be outliers in that HCC failure rate group, and treats the 2019 benefit year as a second pilot year for RXC validation.

• **Medical Loss Ratio.** New requirements for MLR reporting on prescription drug coverage—drug rebates and price concessions—are finalized as proposed with technical updates and an update to require the data be reported beginning with the 2022 plan year, rather the 2021 plan year as proposed. Proposals related to MLR accounting for individual market wellness incentives and proposals related to outsourced activities were also finalized as proposed.

A press release and fact sheet for the final rule are also available. The rule will be published in the Federal Register on May 14. In addition to the final rule, CMS issued additional guidance including the 2021 Letter to Issuers in the Federally-facilitated Exchanges, a Revised Rate Review Bulletin, and the final Key Dates for Calendar Year 2020.

**Why this matters:** The 2021 Notice of Benefit and Payment Parameters provides guidance to insurers offering qualified health plans (QHPs) on federal and state exchanges. Each year CMS issues a Notice of Benefit and Payment Parameters for the upcoming benefit year.

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**Federal COVID-19 Policy Guidance and Other Developments**
HHS Details Emergency Fund Distribution to Rural, Hotspot Hospitals: The Department of Health and Human Services last week distributed $22 billion from the Public Health and Social Services Emergency Fund to hospitals with high numbers of COVID-19 admissions, as well as rural hospitals and clinics.

Specifically, $12 billion was allocated to hospitals with at least 100 COVID-19 inpatient admissions through April 10, 2020. Another $10 billion went to all critical access hospitals, in addition to general acute-care hospitals, rural health clinics and community health centers located in rural areas.

FDA Authorizes First Antigen Test to Rapidly Detect COVID-19 Virus: The Food and Drug Administration Friday issued the first emergency use authorization for a COVID-19 antigen test, which can quickly detect the SARS-CoV-2 virus in a nasal swab sample.

Under the EUA, high and moderate complexity laboratories certified under the Clinical Laboratory Improvement Amendments and point-of-care facilities with a CLIA certificate of waiver, compliance or accreditation may use the test, made by Quidel Corporation.

Antigen tests are faster and generally less costly than polymerase chain reaction tests, but have a higher chance of false negatives, meaning negative results may need to be confirmed with a PCR test, FDA said.

Morphine Sulfate, Epinephrine Added to FDA’s List of Drugs with COVID-19 Compounding Flexibility: The Food and Drug Administration May 8 expanded the list of drugs covered under newly flexible compounding policies to include two that may be in short supply because of the COVID-19 pandemic: morphine sulfate and epinephrine.

Under the temporary policy, which is to remain in effect for no longer than the duration of the COVID-19 public health emergency, FDA said it does not intend to take action against pharmacies for compounding drug products that are essentially copies of commercially available drugs or for providing drugs to hospitals without first obtaining patient-specific prescriptions, as long as certain circumstances outlined in the guidance are present and other conditions established in section 503A of the Federal Food, Drug, and Cosmetic Act are met.

CDC Data Tool Shows COVID-19 Testing, Cases: The Centers for Disease Control and Prevention last week launched the COVID-19 Data Tracker, a website showing data on U.S. laboratory testing and cases reported to CDC from state health departments and territorial jurisdictions. The site currently shows aggregate testing and case data and county-level case data, as well as data on school closures and other “social impact” events. CDC plans to add county-level testing data in the future. The number of positive tests in a state does not equal the number of cases, because a patient can be tested more than once and not all laboratory tests are reported to CDC.

AHA Urges FCC to Extend COVID-19 Program to All Direct Care Facilities: The American Hospital Association urged the Federal Communications Commission to grant expedited approval to its request that the agency extend the COVID-19 Telehealth Program to all hospitals and other direct patient care facilities, regardless of their size, location, or for-profit or not-for-profit status.

CMS Issues New COVID-19 FAQs on Medicaid and CHIP: The Centers for Medicare & Medicaid Services recently issued new Frequently Asked Questions to aid the Medicaid program and Children's Health Insurance Program in their response to the COVID-19 pandemic. The new FAQs cover a variety of Medicaid and CHIP topics, including provider payment, eligibility and enrollment flexibilities.
Of particular interest to hospitals are a series of FAQs that address Upper Payment Limit requirements and methodologies, provider payment increases related to COVID-19, and added flexibility for hospital presumptive eligibility.

**FDA Authorizes First At-home COVID-19 Diagnostic Test Using Saliva Specimens:** The Food and Drug Administration issued an emergency use authorization to Rutgers Clinical Genomics Laboratory for the first COVID-19 diagnostic test with the option of using home-collected saliva samples. Once patients collect their saliva sample, they return it to RCGL in a sealed package for testing. "This provides an additional option for the easy, safe and convenient collection of samples required for testing without traveling to a doctor's office, hospital or testing site," said FDA Commissioner Stephen Hahn, M.D.

**FDA Says Certain Respirators From China No Longer Authorized for Emergency Use:** The Food and Drug Administration revised its April 3 emergency use authorization for N95 and similar respirators made in China to remove certain respirators that failed to demonstrate at least 95% particulate filtration efficiency when tested by the National Institute for Occupational Safety and Health. Health care personnel should not use these respirators as personal protective equipment but may use them as face masks, FDA said. The unauthorized models are made by: CTT Co. Ltd; Daddybaby Co. Ltd; Dongguan Xianda Medical Equipment Co. Ltd.; Guangdong Fei Fan Mstar Technology LTD; Guangdong Nuokang Medical Technology Co. Ltd.; Huizhou Huinuo Technology Co. Ltd.; and Lanshan Shendun Technology Co.

**CDC Streamlines Lab Test Result Reporting by Sharing COVID-19 Results Reported to Public Health Agencies with HHS System:** To streamline the reporting of COVID-19 lab test results, the Centers for Disease Control and Prevention encouraged all U.S. hospital laboratories to submit their COVID-19 testing information to their state or local public health department following their normal protocol for reportable conditions. In turn, the state/local health departments will report the data to CDC, and CDC will submit the data to the Department of Health and Human Services’ Protect System. HHS last month asked hospitals to use the HHS Protect System to report in-house laboratory testing results. Hospitals that report data to their state/local health departments do not need to also submit it to the HHS Protect System, the CDC said. However, hospital laboratories may opt to continue reporting testing data directly into the HHS Protect System following HHS instructions. For details on how to report test data, see the CDC guidance.

**HHS Updates FAQs Related to CARES Act Emergency Funds:** The Department of Health and Human Services released updated FAQs related to payments from the Public Health and Social Services Emergency Fund.

Among other areas, the updated FAQs specify that HHS generally does not intend to recoup any funds, or so-called "overpayments" as long as a provider’s lost revenue and increased expenses exceed the amount of funding received; discuss the definition of individuals with possible or actual cases of COVID-19; and cover the terms and conditions of the fund, including oversight and enforcement mechanisms HHS will use, balance billing, reporting requirements and rejecting payments.

The Coronavirus Aid, Relief, and Economic Security Act and Paycheck Protection Program and Health Care Enhancement Act included $175 billion in the Public Health and Social Services Emergency Fund to reimburse health care providers for health care-related expenses or lost revenues not otherwise reimbursed that are attributable to COVID-19.
HHS Extends Attestation Deadline for Emergency Funds: The Department of Health and Human Services has extended the deadline for health care providers to attest to receipt of payments from the Public Health and Social Services Emergency Fund and accept the terms and conditions. Providers will now have 45 days, increased from 30 days, from the date they receive a payment to attest and accept the terms and conditions or return the funds. For example, the initial 30-day deadline for providers who received payment on April 10, is extended to May 24 from May 9. With the extension, not returning the payment within 45 days of receipt of payment will be viewed as acceptance of the terms and conditions.

HealthEquip App Continues to Facilitate PPE Matches: Last month, the American Hospital Association announced the availability of HealthEquip, a new app-powered resource matching hospitals in need of personal protective equipment with organizations donating PPE. HealthEquip was developed through a partnership with Microsoft, Kaiser Permanente, consulting firm Kearney, Merit Solutions and UPS. Work continues to further facilitate needed donations – this includes donations of available PPE, as well as financial donations to support manufacturing new PPE. Organizations with available PPE can continue registering supplies through HealthEquip. In addition to the HealthEquip app, AHA continues to expand available resources for the hospital field through the 100 Million Mask Challenge by fostering new partnerships and exploring all options and resources to best support our health care workforce.

HHS Reminds Health Care Providers of HIPAA’s Privacy Provisions for Media Coverage: The Department of Health and Human Services reminded health care providers that HIPAA privacy rules bar them from giving media and film crews access to facilities where patients’ protected health information is accessible without the patients’ prior authorization, even during the current COVID-19 public health emergency. The reminder, issued by the agency’s Office for Civil Rights, explains that covered health care providers are still required to obtain valid HIPAA authorizations from each patient whose PHI will be accessible to the media and this must be done before the media is given access to that PHI. Masking or obscuring patients’ faces or identifying information before broadcasting a recording of a patient is not sufficient. The reminder also discusses safeguards that the agency deems “reasonable” for protecting patients’ privacy whenever the media is granted access to facilities.

New Resource on Serologic Tests and Surveillance Strategy for COVID-19: The Centers for Disease Control and Prevention recently launched a webpage to provide information about an agency-developed serologic test to detect SARS-CoV-2 antibodies. CDC says its test has a specificity of greater than 99% and a sensitivity of 96% based on initial tests.

The test is not currently designed for individual use. Rather, CDC plans to use its antibody testing as part of a broad surveillance effort to better understand how much of the U.S. population has been infected with SARS-CoV-2 and how the virus is spreading through the population over time.

CDC is also collaborating with other government agencies to evaluate commercially developed serology assays. More information about these studies can be found on the Federal Laboratory Consortium for Technology Transfer webpage.

FDA Issues Policy for Manufacturers to Prevent Medical Device Shortages: The Food and Drug Administration issued guidance implementing section 3121 of the Coronavirus Aid, Relief, and Economic Security Act, which requires manufacturers to notify FDA of a permanent discontinuance or significant interruption in the manufacture of certain medical devices to prevent or mitigate shortages during the COVID-19 emergency. FDA said the guidance aims to clarify and make recommendations regarding who must notify FDA and how, and what information to include in the notification.
The FDA authorized the first serology test in which independent federal data provided the scientific evidence used to support the authorization. EUROCIMMUN US Inc.’s Anti-SARS-CoV-2 ELISA (IgG) test, which will aid in identifying individuals with an adaptive immune response to SARS-CoV-2, is certified for emergency use by Clinical Laboratory Improvement Amendments-certified labs. FDA said the results that secured the test’s authorization are among the first to come from a collaborative effort by the FDA, National Institutes of Health, Centers for Disease Control and Prevention and Biomedical Advanced Research and Development Authority to evaluate certain serological tests.

CDC Says Evidence Supports SARS-CoV-2 Transmission While Presymptomatic or Asymptomatic: SARS-CoV-2 may spread from individuals who are presymptomatic or asymptomatic, according to a new Centers for Disease Control and Prevention report based on epidemiologic, virologic and modeling studies before CDC recommended widespread use of face masks. The authors said the findings imply that the case-fatality rate may be lower than currently estimated, and reinforce the value of community interventions to stop the spread of the virus in the absence of symptoms.

CDC Updates Guidance for COVID-19 Isolation, Health Care Work Safety: The Centers for Disease Control and Prevention updated guidance designed to keep health care personnel safe during the COVID-19 pandemic, along with patient isolation strategies to ensure consistency in CDC’s criteria for patient discontinuation of transmission-based precautions and health care personnel return-to-work guidance.

CDC’s updated symptom-based strategy for discontinuing isolation for COVID-19 patients and health care personnel now recommends a uniform “10-and-3” policy in which isolation is maintained for at least 10 days after illness onset and at least three days after recovery. In this guidance, CDC defines illness onset as the date symptoms begin; recovery is defined as fever resolution without the use of fever-reducing medications and progressive improvement or resolution of other symptoms.

The agency also issued updated and revised policies for the following:

- Return-to-work criteria for health care personnel with confirmed or suspected COVID-19;
- Evaluation and testing of individuals for COVID-19; and
- Discontinuation of transmission-based precautions and disposition of patients with COVID-19 in health care settings.

AHA Report Examines Five New COVID-19 Forecasting Models: In its recently updated report “COVID-19 Models: Forecasting the Pandemic’s Spread,” the American Hospital Association looks at five new COVID-19 forecasting models, including two free AHA tools to help visualize the nation’s hospital bed capacity.

The AHA's COVID-19 Bed Occupancy Projection Tool shows total hospital beds and adult intensive care unit beds by state, Health Referral Region and Health Service Area; potential bed shortages by state in various scenarios; and share of beds occupied by non-COVID patients. It also locates individual health care facilities on an interactive map, tailoring results by poverty and uninsured rates.

The People Per Hospital Bed Map shows population per bed as a measure of capacity for adult beds and adult ICU beds.

Report Shows Nation’s Hospitals Losing About $50B a Month Fighting Pandemic: In a new report, the American Hospital Association estimates that the financial impact to hospitals and health systems from
COVID-19 expenses and revenue losses over the four-month period from March 1 and June 30 totals $202.6 billion, with losses averaging over $50 billion per month.

The estimate includes the costs of COVID-19 hospitalizations, canceled and foregone services, purchasing needed personal protective equipment and providing additional support to hospital workers.

The Centers for Medicare & Medicaid Services (CMS) posted new Frequently Asked Questions (FAQs) to aid state Medicaid and Children’s Health Insurance Program (CHIP) agencies in their response to the COVID-19 pandemic. The new FAQs cover a variety of Medicaid and CHIP topics, including:

- Emergency Preparedness and Response;
- Eligibility and Enrollment Flexibilities;
- Benefit Flexibilities;
- Cost-Sharing Flexibilities;
- Financing Flexibilities
- Managed Care Flexibilities;
- Information Technology; and
- Data Reporting.

The new FAQs have been integrated into the previously released COVID-19 FAQ document, which has been reorganized with a more comprehensive table of contents.

CMS also updated their FAQ document on Medicare FFS billing. The FAQs cover a wide range of billing questions for all settings, and includes updates on both Accountable Care Organizations and the Merit-based Incentive Payment Program.

The National Institute of Standards and Technology (NIST) developed new resources to allow researchers to get the most from the COVID-19 Open Research Dataset (CORD-19), a collection of scientific literature about coronaviruses containing tens of thousands of items.

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**Court Hears Arguments in AHA Lawsuit Over Public Disclosure of Negotiated Rates**

On May 7, a federal district court in Washington, D.C., heard oral arguments in the American Hospital Association’s legal challenge to the Centers for Medicare & Medicaid Services’ final rule mandating that hospitals disclose their privately negotiated charges with commercial health insurers.

The court engaged in a detailed discussion with both counsel for the AHA and the government about the Department of Health and Human Services’ statutory authority to require and enforce the provision that mandates public disclosure of individually negotiated rates between commercial health insurers and hospitals under the authority it has to compel disclosure of “standard charges.”

AHA counsel emphasized that the agency’s current view of its authority was not consistent with the statute’s text or the agency’s previous views of the meaning of the statute, and that it’s now expansive view of what must be disclosed as standard charges does not give patients information they most want and need about their out-of-pocket costs.
Counsel for the government maintained that the agency developed the rule to foster transparency for patients and allow them to be better consumers of care in a way that is least burdensome for hospitals.

Joining the AHA in the lawsuit are the Association of American Medical Colleges, the Children’s Hospital Association, and the Federation of American Hospitals, as well as three member hospitals.

Why this matters: There is no specific timeframe for a ruling, but the court indicated that it will try to quickly issue a decision, understanding that with a January 1, 2021, compliance deadline, hospitals will need to immediately begin work related to that effort.

In addition to hospitals fundamentally opposing the rule, there are serious concerns that hospitals will not have adequate time to meet the implementation date of January 1, 2021 due to the COVID-19 pandemic.

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**CMS Proposes Additional Annual Payment Increases for Providers in FY 2021**

**Hospital Inpatient Prospective Payment System:** The Centers for Medicare & Medicaid Services issued a proposed rule that would increase Medicare inpatient prospective payment system rates by a net 3.1% in fiscal year 2021, compared to FY 2020, for hospitals that are meaningful users of electronic health records and submit quality measure data. In addition, the rule would require disclosure of certain payer-negotiated rates and makes changes to Disproportionate Share Hospital payments, Chimeric Antigen Receptor T-cell (CAR T) therapy payment, and quality incentive programs.

CMS proposes to require hospitals to report on the Medicare cost report the median payer-specific negotiated rates for inpatient services, by Medicare Severity-Diagnosis Related Group, for Medicare Advantage organizations and third party payers. This would be in effect for cost reporting periods ending January 1, 2021 or after. The agency also solicits feedback on using these rates as the basis for the DRG weights.

For FY 2021, the agency estimates that it will distribute $7.82 billion in disproportionate share hospital payments, a decrease of approximately $530 million compared to FY 2020. In addition, CMS proposes to use a single year of uncompensated care data from the 2017 Medicare cost report to determine the distribution of DSH uncompensated care payments for FY 2021.

CMS also creates a new MS-DRG for CAR T based on available Medicare claims data.

For the inpatient quality reporting program, CMS proposes to, starting with the calendar year 2021 reporting period, gradually increase the number of quarters of electronic clinical quality measure data required until it reaches a full year for the CY 2023 performance period. CMS also proposes to begin publicly reporting eCQM measure results in late 2022, starting with data from CY 2021.

For a fact sheet on the proposed rule (CMS-1735-P), click here. CMS will accept comments on the proposed rule through July 10.

**Long-term Care Hospital Prospective Payment System:** CMS issued a proposed rule for the long-term care hospital prospective payment system for fiscal year 2021. Under the rule, net payments for LTCHs would decrease by 0.9% (-$36 million) relative to FY 2020 payments. This net decrease is largely due to a reduction in payment for site-neutral cases, which account for 25% of all cases. This reduction comes
because, in FY 2021, all site-neutral cases will begin to be paid the full site-neutral rate, rather than the higher, blended rate. CMS proposed no changes or updates to the LTCH quality reporting program.

**Why this matters:** These proposed rules follow several others released over the last several weeks and are issued on an annual basis to reflect payment system updates and other policy changes for the following fiscal year.

One of the most significant provisions in the IPPS proposed rule is the proposal to collect a summary of certain data already required to be disclosed by CMS’ 2019 price transparency rule, specifically hospitals’ median payer-specific negotiated inpatient services charges for Medicare Advantage organizations and third party payers. In addition, the agency is requesting information regarding the potential use of these data to set relative Medicare payment rates for hospital procedures. The hospital industry continues to strongly oppose the price transparency rule, and is closely watching the outcome of legal action to block implementation.

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**HHS Announces Allocation Plan for Remdesivir; Requests Weekly Data from Hospitals to Inform Distribution**

The Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response (ASPR) announced the allocation plan for the drug remdesivir. The allocation is from a donation by Gilead Sciences, Inc. to the United States which was finalized on May 3, 2020.

The donated doses of the treatment, which received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration, will be used to treat hospitalized COVID-19 patients in areas of the country hardest hit by the pandemic.

Beginning on the evening of May 7, 2020, the process was initiated to deliver cases of the drug to the following states: Connecticut (30 cases), Illinois (140 cases), Iowa (10 cases), Maryland (30 cases), Michigan (40 cases) and New Jersey (110 cases). Each case contains 40 vials of the donated drug. ASPR expects cases to be delivered to all 50 states as well as territories and the Veterans Health Administration and the Indian Health Service for distribution within those health systems.

Gilead Sciences, Inc. committed to supplying approximately 607,000 vials of the experimental drug over the next six weeks to treat an estimated 78,000 hospitalized COVID-19 patients under the EUA granted by the FDA. Preliminary results suggest that remdesivir is associated with faster recovery, although the data was not sufficient to determine if the drug was associated with lower mortality. In addition to the donated doses for hospitalized patients in the United States and other countries, remdesivir also is available in the U.S. through clinical trials.

**Why this matters:** Healthcare providers and hospitals interested in administering the donated experimental drug will be required to work with their state health department. State health departments will distribute the doses to appropriate hospitals in their states because state and local health departments have the greatest insight into community-level needs in the COVID-19 response, including appropriate distribution of a treatment in limited supply. Candidates for the donated doses must be patients on ventilators or on extracorporeal membrane oxygenation or who require supplemental oxygen due to room-air blood oxygen levels at or below 94 percent.
As part of the distribution plan, HHS announced that it is requesting certain data from hospitals to inform distribution of its supply of remdesivir. Specifically, HHS is requesting weekly data on the number of currently hospitalized COVID-19 patients and, of those hospitalized, the number requiring placement in intensive care units (ICUs). The initial data are due by 8:00 p.m. EST May 12. HHS indicated it intends to ask hospitals to report these data weekly, and that additional details are forthcoming later this week.

HHS asks hospitals to submit the data using its TeleTracking web portal. This is the same portal HHS used last month for a one-time data request to inform its targeted distribution of funds to hospitals heavily impacted by COVID-19. TeleTracking also is one of the options hospitals can use to fulfill HHS’s previous request for the daily reporting of bed capacity and utilization data.

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**CMS Issues Relief For Certain Beneficiaries for Medicare Enrollment**

In response to concerns raised by BCBSA, CMS issued a policy addressing delays in enrollment and provided “relief” for those who experienced delays. The “relief” will be extended to eligible persons through June 17 and affects those in their initial open enrollment period or those in an SEP.

**Why this matters:** Many beneficiaries faced issues as to their enrollment in Medicare given the closure of Social Security offices during the national emergency and the fact that many may have had a delay in their Medicare Part B enrollment.

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**State Issues**

**Delaware**

Regulatory

**Governor Announces June 1 as “Targeted Date” for Phase I of Economic Reopening: State of Emergency Extended through May 31**

Governor John Carney announced June 1, 2020 as the target date for Phase I of Delaware’s economic reopening. Governor Carney has extended Delaware’s State of Emergency declaration, including the stay-at-home order and its other modifications, to May 31, 2020. Part of Phase 1 includes the resumption of elective surgeries. The June 1 target date is contingent upon compliance with social distancing and other requirements placed on businesses during the interim phase, and on public health data.

Based on federal recommendations, phase I would include:

- Vulnerable individuals shelter in place;
- Maintain social distancing in public;
- Limit gatherings to ten (10) individuals;
- Minimize non-essential travel, personal and business;
- Encourage teleworking;
- Return to work in phases;
- Consider special accommodations for vulnerable persons in the workforce;
- School and youth activities remain closed;
- No visits to senior living facilities or hospitals;
- Large venues and restaurants would have strict guidelines;
- **Elective surgeries resume**;
- Gyms follow strict social distancing and sanitation protocols; and
Bars remain closed

During this briefing the Governor also announced a significant expansion of Delaware’s statewide testing program for COVID-19 as Delaware moves toward Phase I of an economic reopening. The plan will be implemented in partnership with Delaware’s hospital systems, primary care physicians, Federally Qualified Health Centers, and community organizations statewide. The new testing program will allow the State of Delaware to conduct 80,000 tests monthly – more than four times the current level of testing statewide. Delaware’s plan is based on guidance from the U.S. Centers for Disease Control and Prevention (CDC). The State of Delaware will prioritize testing under the new statewide program for:

- Any symptomatic individual;
- Anyone with known exposure to COVID-19;
- Vulnerable Delaware populations, including elderly Delawareans and members of low-income communities; and
- Certain front-line essential workers.

Governor Issues His 16th State of Emergency Modification
On May 10, 2020 Governor John Carney signed the sixteenth modification to his State of Emergency declaration, suspending end-of-year evaluations for educators, professional development requirements and assessments due to the suspension of the school year caused by COVID-19. Governor Carney’s latest modification holds Delaware’s students and educators harmless for the shortened school year, also waiving the required learning hours for students and teacher days. School districts and charter schools must still complete remote learning plans submitted to the Delaware Department of Education.

Governor Carney Reschedules Presidential Primary for July 7
Governor John Carney on Thursday rescheduled Delaware’s presidential primary for July 7. Governor Carney’s order to reschedule the election also included the following changes:

- The Delaware Department of Elections will mail absentee ballot applications to all registered Democrats and Republicans in the State of Delaware, providing all eligible registered Delaware voters the opportunity to vote by absentee ballot in the presidential primary election;
- Voters must return the application to the Delaware Department of Elections or complete the process online to receive an absentee ballot;
- The Delaware Department of Elections will operate at least six polling places in each county to allow voters to cast ballots in person should they choose not to vote by absentee ballot; and
- The order requires districts and municipalities to enforce social distancing during elections, require face coverings, and limit crowds to 10 or fewer people at polling places.

State Issues

Pennsylvania

Legislative

House Approves Coronavirus Testing Measure
Legislation that would allow a county or municipal health department to implement a serology test to identify antibodies to the COVID-19 virus was approved by the Pennsylvania House of Representatives. Prior to
final passage, the House Appropriations Committee amended the bill with language that mirrors federal law regarding COVID-19 testing reporting.

**House Bill 2455**, which passed by a 201-1 margin, includes the following requirements:

- The governor must submit a plan, in consultation with the Secretary of Health, for the procurement and disbursement of testing kits or equipment for COVID-19 to the House and Senate Appropriations Committees;
- The secretary of health must authorize state labs to facilitate testing within 72 hours of receipt of the notification;
- Provides for COVID-19 emergency testing procurement and disbursement;
- Establish a list of categories of individuals who serve an essential health and safety function or who are at high-risk of contracting COVID-19; and
- Include a description of how the plan supports efforts to limit the spread of COVID-19 at life-sustaining and other businesses.

The proposal has been sent to the Senate for further consideration.

**Mental Health Compliance Bills Clear House of Representatives**

Two proposals addressing mental health parity law were passed unanimously by the House of Representatives:

- **House Bill 1439** would require an officer of an insurance company to certify that the insurer has completed a comprehensive review of its policies for compliance with the requirements of the federal Mental Health Parity and Addiction Equity Act.
- **House Bill 1696** would require insurers that cover behavioral health services to submit certain information each year to the Pennsylvania Insurance Department (PID) to ensure that the insurers are compliant with the federal Mental Health Parity and Addiction Equity Act.

House Bills 1439 and 1696 will be referred to the Senate for further consideration.

**Governor Wolf Signs Telepsychology Licensure Legislation**

Governor Tom Wolf has signed legislation authorizing Pennsylvania to enter into the Psychological Interjurisdictional Licensure Compact (PSYPACT). **Act 19 of 2020**, formerly Senate Bill 67, permits the following:

- Regulates the practice of telepsychology by psychologists across state boundaries; and
- Permits licensed psychologists to apply for certification that permits the practice of telepsychology or the temporary in-person, face-to-face practice of psychology across state boundaries for 30 days within a calendar year.

The compact does not apply to permanent in-person, face-to-face practice. Act 19 of 2020 is effective July 7, 2020.

By joining the compact, **PSYPACT**, Pennsylvania will have a voting representative on the Psychology Interjurisdictional Compact Commission, the national governing body overseeing the compact. Under the compact, licensed psychologists can apply for multiple certifications to practice tele-psychology and temporary in-person sessions in states participating in the compact. The compact enables a practitioner to practice across state lines without the need to hold multiple licenses in multiple states.
Flexibilities Granted for Background Check Requirements for Employment

House Bill 360, introduced by Representative Jesse Topper (R-Bedford), was amended by the Senate to include legislative language to address barriers to obtaining background checks and fingerprinting due to the closure of locations and decreased staff compliment during the COVID-19 pandemic.

The amended bill was quickly taken up by the House of Representative, which concurred with the changes inserted by the Senate. Governor Wolf has signed this into law as Act 18 of 2020.

Act 18 provides flexibilities for individuals whose background checks must be recertified and those individuals who need their initial background checks completed for employment. Individuals whose current background checks are set to expire have been granted an extension until December 31, 2020, to obtain their recertification.

Individuals who need their initial background checks may commence employment prior to obtaining the certification if all of the following apply:

- The individual has been a Pennsylvania resident during the previous ten-year period
- The individual has submitted the Pennsylvania state criminal check and the child abuse clearance from the Department of Human Services to the employer
- The employer must document the reason that the individual is unable to obtain and submit the FBI fingerprinting background check
- The individual affirms in writing that the individual is not disqualified from employment or has not been convicted of an offense

Act 18 will expire on December 31, 2020, or 60 days after the emergency declaration has been lifted, whichever one comes first. The Department of Human Services plans to post more information regarding Act 18—as well as frequently asked questions—at their website.

State Issues

Pennsylvania

Regulatory

Department of Health Releases Revised Dental Health Care Guidance

The Pennsylvania Department of Health released the revised dental health care guidance as part of Pennsylvania’s phased COVID-19 reopening plan. Governor Wolf and Secretary of Health Dr. Rachel Levine have revised their business closure orders issued on March 19 to remove the prohibition on non-urgent and non-emergent, dental procedures. Those orders were issued on May 7.

Dental providers must follow protocols outlined by the CDC and OSHA for all procedures. If they are unable to follow protocols, then the procedure should not be done. Providers may perform non-aerosolizing, non-urgent and non-emergent care only if proper personal protective equipment, per OSHA guidance, is available for all dental care practitioners, including dental hygienists. Providers should regularly check CDC guidance when providing care as recommendations and guidance could change frequently.
All patients should be screened for symptoms of COVID-19 before arriving at office and social distancing should be maintained while in the office. Patients should wash or sanitize their hands frequently and wear a mask when not undergoing treatment. Tele-dentistry should continue when possible as patients may be able to be treated virtually with antibiotics and pain medication.

**Governor Wolf Announces More Counties Will Move to Yellow Phase**

Governor Wolf announced on Friday that 13 more counties will open in Southwestern Pennsylvania on Friday, May 15 at 12:01 AM. They join the 24 counties which were reopened on May. Those counties include: Allegheny, Bedford, Blair, Butler, Cambria, Fayette, Fulton, Greene, Indiana, Somerset, Washington, and Westmoreland. Beaver County remains in the red phase due to the number of COVID-19 cases in that county. The rest of the counties remain in the red phase. Those in the yellow counties will be monitored for any increases in COVID-19 cases. If counties do not continue to meet the metrics established by the state they can move back to red.

**During the yellow phase:**
- Stay at home restrictions are lifted in favor of aggressive mitigation
- Large gatherings are still prohibited;
- In person retail is allowed with appropriate social distancing rules in place (Curbside /Delivery preferred);
- Masks are still required in public;
- Restaurants/Bars limited to carry out and delivery; and
- Indoor recreation, gyms, spas, hair and nail salons, casinos, and theaters remain closed.

**Patient Safety Authority Annual Report Highlights Progress in Patient Safety**

Pennsylvania's Patient Safety Authority (PSA) has released its 2019 Annual Report. The report highlights activities of the PSA, including its September 2019-launched quarterly peer-reviewed journal, Patient Safety. It also includes an analysis of patient safety events reported into the Pennsylvania patient safety reporting system (PA-PSRS), a secure database that collects health care facility data on “serious events” and “incidents.”

**Report highlights:** In both 2018 and 2019, 97% of reports were defined as “incidents” and three percent were “serious events.” Reporting rates have increased significantly in recent years and in 2019, were up 26% from 2015 reporting levels. Across acute care settings, the most common event in each of the last five years were “errors related to procedure/treatment/test” (33% of all acute care event reports).

Other events in 2019 included:
- Medication errors (18%);
- Complication of procedure/treatment/tests (16%); and
- Falls (11%).

PSA researchers and analysts note that “the increase in reporting rates each year may reflect improvements in patient safety culture across the Commonwealth....”

**Why this matters:** The PSA, created during 2002, promotes patient safety by analyzing data and making recommendations about steps that providers can take to prevent similar events from happening in the
future. The report identifies areas of harm that health care providers should take to minimize events (e.g. telemetry monitoring, infant falls, and IV pump issues).

State Issues

West Virginia
Regulatory

Week 3 of Reopening West Virginia Moves Forward
Next Monday, West Virginia will be entering week 3 of its reopening plan. This phase, which is intentionally scaled back following the first peak of COVID-19 cases statewide, permits only drive-in movie theaters and a limited number of fitness centers authorized to reopen.

According to WV COVID-19 Czar Dr. Clay Marsh, after observing the increase in coronavirus cases that occurred in two states following business reopening activity – Texas, which had its highest two-day increase in positive cases over the weekend, and Georgia, where cases have shot up after that state effectively ended its lockdown – West Virginia is exercising caution.

Not wanting to see a spike in infections, only drive-in movie theaters, which number less than a half-dozen in the state, and wellness centers operated by licensed health providers for physical and exercise therapy and post-op rehabilitation, will be able to reopen on May 11. They join the reopening of nail and beauty salons, barber shops, nonretail businesses with fewer than 10 employees, outdoor dining at restaurants, and church and funeral services.

Executive Order Requires COVID-19 Testing in Assisted Living and Residential Care Communities
Governor Justice issued May 6 a new Executive Order 35-20 requiring the Department of Health and Human Resources (DHHR), with the assistance of the West Virginia National Guard (WVNG), to test the following individuals:
- All individuals who reside or work in assisted living residences and residential care communities unless individuals have previously been tested under Executive Order 27-20; and
- All individuals who work in child care centers.

Local health departments and other county or city agencies throughout the State are directed to provide any and all assistance and/or resources as may be requested by the DHHR and WVNG to effectuate the terms of the Order.

The order follows Governor Justice’s decision to require COVID-19 testing at all West Virginia nursing homes.
Interested in reviewing a copy of a bill(s)? Access the following web sites:

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

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