Federal Issues

Legislative

Capitol Hill Coronavirus Activity

Last week, House Majority Leader Steny Hoyer (D-MD) announced House Members would not come back to Washington, D.C. this week after consulting with the Office of the Capitol Attending Physician. However, Senate Majority Leader Mitch McConnell (R-KY) plans to bring the Senate in session to resume consideration of judicial nominations. Elsewhere on the Hill:

- The House Appropriations Committee’s Labor-HHS-Education Subcommittee announced it will hold an in-person hearing on Wednesday on the federal government’s response to the coronavirus pandemic.
- Last Wednesday, House Speaker Nancy Pelosi announced that six Democrats will join Majority Whip Jim Clyburn (D-SC) on the House Select Committee on the Coronavirus Crisis. The members joining the committee are: Reps. Maxine Waters (D-CA), Carolyn Maloney (D-NY), Nydia Velázquez (D-NY), Bill Foster (D-IL), Jamie Raskin (D-MD), and Andy Kim (D-NJ).

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- A broad coalition led by America’s Health Insurance Plans, the Blue Cross Blue Shield Association, the American Hospital Association, and the U.S. Chamber of Commerce sent a letter to Congress urging immediate action to support employers and workers in their response to the COVID-19 crisis by protecting and expanding high quality, affordable health care coverage. Specifically, the letter asks Congress to:
  o Provide employers with temporary subsidies to preserve current health benefits;
  o Cover the cost of coverage through the Consolidated Omnibus Budget Reconciliation Act (COBRA);
  o Expand use of Health Savings Accounts (HSAs);
  o Open a Special Enrollment Period (SEP) for health insurance marketplaces; and
  o Increased eligibility and federal financial assistance to buy coverage in the health insurance marketplaces.

- House Energy and Commerce Committee members Dianna DeGette (D-CO) and Fred Upton (R-MI) released a concept paper outlining six main components for a follow-up to the 21st Century Cures Act. The proposal aims to safely and efficiently modernize the delivery of health care in the wake of the coronavirus pandemic through:
  o Public health and pandemic preparedness;
  o Caregiver integration;
  o Patient engagement in health care decision-making;
  o Diversity in clinical trials;
  o Modernization of the FDA’s digital health regulatory framework; and
  o CMS modernization and coverage of emerging technologies.

Supreme Court Rules in Favor of Plans in ACA Risk Corridors Lawsuit

On April 27, the U.S. Supreme Court issued an 8-1 decision in Maine Community Health Options, Inc. v. United States. The case was brought by Moda Health and was consolidated with cases brought by BCBS of North Carolina, Maine Community Health Options and Land of Lincoln Mutual Health Insurance Co. for review by the Supreme Court.

Why it matters: The ruling was a significant victory in the long-standing effort of health plans to recover unpaid transitional risk corridors amounts owed from the early years of the Affordable Care Act (ACA). It paves the way for recovery of the full $12.3 billion in damages to be paid collectively to all plans that did not receive full payment for risk corridors in the individual and small group markets for years 2014-2016.

The decision, written for the majority by Justice Sony Sotomayor, addressed three key points:
The ACA obligated the Government to pay participating insurers the full amount under the statute; the payment obligation was not overridden by Congress’ enactment of later appropriations riders; and the petitioning health plans correctly sought recovery of unpaid risk corridors amounts by filing their lawsuits in the U.S. Court of Federal Claims.

On behalf of the industry, AHIP issued a statement highlighting appreciation for the court’s favorable decision and noting that the ruling simply ensures that the federal government complies with obligations it agreed to for services the private sector already delivered.

Federal Issues
Regulatory

Court Upholds Block on Immigrant Proof of Coverage Pending Appeal
The U.S. Court of Appeals for the 9th Circuit denied the federal government’s request to lift pending appeal in a preliminary injunction blocking a presidential proclamation restricting family-sponsored immigrants from entering the United States without acquiring specified health insurance.

Issued on October 4, 2019, the Proclamation barred, with some exceptions, individuals seeking to enter the United States on an immigrant visa from entering unless they could demonstrate that they will be covered by certain approved health insurance within 30 days of entry or that they have the resources to cover foreseeable healthcare costs.

A coalition last year filed a class-action lawsuit challenging the proclamation and an associated emergency information collection notice that provided less than 48 hours to comment. A federal judge in Oregon then granted a nationwide preliminary injunction blocking the proclamation until the litigation is resolved.

The appeals court today said the government “has not established the requisite irreparable harm necessary to justify a stay pending appeal.”

Federal COVID-19 Policy Guidance and Other Developments
HHS This Week to Send Relief Funds to Hospitals in COVID-19 Hot Spots, Rural Areas: The Department of Health and Human Services this week will begin distributing an additional $22 billion in funds from the Public Health and Social Services Emergency Fund. HHS on Friday said hospitals with at least 100 COVID-19 inpatient admissions through April 10 will receive $12 billion in funds; and general acute-care hospitals, critical access hospitals, rural health clinics and community health centers located in rural areas will receive $10 billion in funds.

The much needed funding will go to hospitals with high numbers of COVID-19 admissions (hot spots) to help offset the significant costs incurred as they are treating COVID-19 patients. Additional funding will also be provided to these hospitals based on their coverage of Medicaid and uninsured patients and rural hospitals to help ensure they are able to remain open and serve their communities.
AHA Requests Clarification of HRSA COVID-19 Uninsured Program: The American Hospital Association Saturday sent the Health Resources and Services Administration a letter requesting clarifications for several elements of the COVID-19 Uninsured Program. Beginning May 6, 2020, providers may submit claims through the program for uninsured patients' COVID-19 testing and treatment. The AHA urged HRSA to clarify coding guidance to ensure consistency with International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) guidelines, as well as reimbursement rates and timing for submitting certain claims.

FDA Tightens Reins on Antibody Testing: The Food and Drug Administration said it is adopting more stringent standards for COVID-19 antibody tests. The agency will boost oversight through new standards of accuracy and require antibody test manufacturers to submit new information proving the testing quality. FDA said it also will require manufacturers to apply for emergency use authorization within 10 business days of their products’ release, with distribution suspended if the test cannot meet the agency’s specificity and sensitivity criteria.

Additionally, FDA stated that laboratories certified for high-complexity testing under the Clinical Laboratory Improvement Amendments, including hospital laboratories, that develop their own laboratory-developed COVID-19 antibody test through an earlier agency policy, are also encouraged to seek an emergency use authorization.

Finally, FDA introduced a more-streamlined process to support EUA submissions and review, with two, voluntary EUA templates for antibody tests made available: one for commercial manufacturers and another for CLIA-certified high-complexity labs who decide to seek FDA authorization. These templates will facilitate the preparation and submission of an EUA request and can be used by any interested developer.

CDC Sets Preliminary Standards for Digital COVID-19 Contact Tracing Tools: The Centers for Disease Control and Prevention last week issued preliminary guidance for the development of forthcoming contact tracing apps that can help slow the spread of COVID-19.

The guidance defines minimum and preferred characteristics of digital contact tracing tools “to help health departments overcome one or more obstacles in the COVID-19 contact tracing workflow.”

The CDC said it based this resource on preliminary research and targeted discussions with contact tracing and informatics experts across county, state and federal government and other stakeholders in the areas of case management and proximity tracking.

HHS Announces Funding to Mitigate COVID-19’s Impact on Vulnerable Communities: The Department of Health and Human Services’ Office of Minority Health May 1 announced it will provide funding to help deliver important COVID-19-related information to racial and ethnic minority, rural and socially vulnerable communities hardest hit by the pandemic.

The funding opportunity will provide up to $40 million for the development and coordination of a strategic network of national, state, territorial, tribal, and local organizations. The information network will work with community-based organizations to strengthen efforts that link communities to COVID-19 testing, health care and social services and to best share and implement effective response, recovery and resilience strategies. Applications are due by 6:00 PM EST on Monday, May 11.
NIH to Study COVID-19 Infection Rate in U.S. Children: The National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, is enrolling 2,000 U.S. families in a study to help determine the COVID-19 infection rate in U.S. children and their family members, and the share of infected children who develop symptoms. The families will participate in the study remotely by mailing nasal swab samples for laboratory analysis and completing online questionnaires. “One interesting feature of this novel coronavirus pandemic is that very few children have become sick with COVID-19 compared to adults,” said NIAID Director Anthony Fauci, M.D. “Is this because children are resistant to infection with SARS-CoV-2, or because they are infected but do not develop symptoms?” The researchers also hope to clarify whether people with asthma or other allergic conditions are less susceptible to infection and severe disease, as preliminary evidence suggests.

DHS, CISA Update Telework Guidance: The Department of Homeland Security and the Cybersecurity and Infrastructure Security Agency have updated their telework guidance to include new guidance on telework best practices, videoconferencing tips, guidance for securing videoconferencing, and specific cybersecurity recommendations for critical infrastructure and federal agencies using video conferencing.

HRSA Issues New Resources on COVID-19 Uninsured Program Portal: The Health Resources and Services Administration hosted webinars for health care providers on the agency’s COVID-19 Uninsured Program Portal. During the webinars, representatives from HRSA and United Health Group, the portal administrator, reviewed the process for submitting claims through the portal. They also announced the release of a number of new resources, including an interactive user guide, a provider checklist for claims reimbursement, and guides on Optum Pay™ direct deposit enrollment and alternative payment routing options. Additional materials will be released in the coming weeks.

CMS Announces Additional COVID-19 Waivers, Rule Changes: The Centers for Medicare & Medicaid Services last week announced additional regulatory waivers and rule changes to expand diagnostic testing for Medicare and Medicaid beneficiaries, telehealth in Medicare, hospital capacity and the health care workforce during the COVID-19 emergency.

The new waivers apply nationwide and are generally retroactive to March 1, 2020. They include waivers that:

- Expand access to COVID-19 testing, including serological and antibody tests;
- Expand flexibility around treatment locations;
- Expand access to telehealth;
- Allow for additional workforce capacity; and
- Eliminate certain administrative requirements.

The telehealth changes, for example, allow hospital outpatient departments to bill for certain Medicare telehealth services, expand the types of providers that can furnish Medicare telehealth services to physical and occupational therapists, speech language pathologists and others, and allow more telehealth services to be provided by audio-only connection.

Other changes allow teaching hospitals to increase their number of temporary beds without facing reduced payments for indirect medical education; and certain provider-based hospital outpatient departments that relocate off-campus to obtain a temporary exception and continue to be paid at the full outpatient prospective payment system rate, rather than the reduced site-neutral rate.
CMS also issued additional FAQs clarifying Emergency Medical Treatment and Labor Act requirements, flexibilities and considerations for hospitals and other providers during the pandemic.

**HHS Awards Funding to Increase Telehealth Access and Infrastructure:** The Department of Health and Human Services, through its Health Resources and Services Administration, awarded $20 million to increase capability, capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents and families. The money will help assist telehealth providers with cross-state licensure to improve access to health care during the pandemic. HRSA’s Maternal and Child Health Bureau awarded a total of $15 million toward supporting key areas in maternal and child health; HRSA’s Federal Office of Rural Health Policy awarded the remaining $5 million to assist telehealth clinicians nationally on licensure and credentialing to meet the emerging needs related to the COVID-19 public health emergency.

**NASA’s COVID-19 Ventilator Gains FDA Approval for Emergency Use:** The Food and Drug Administration approved for emergency use a ventilator specially developed by the National Aeronautics and Space Administration to treat COVID-19 patients. NASA’s VITAL (Ventilator Intervention Technology Accessible Locally) system is designed to last three to four months and is specifically tailored for patients with COVID-19 by providing respiratory support for patients experiencing respiratory failure or insufficiency. Additionally, the device is designed to be built with components outside the current medical device supply chain and thereby will not impact existing ventilator supply chains.

**CMS Commission to Assess Nursing Home Response to COVID-19:** An independent commission will assess the response to COVID-19 and offer recommendations to nursing homes, the Centers for Medicare & Medicaid Services announced last week. Made up of industry experts, family members, clinicians, patient advocates and others, the commission will consider three areas: protecting residents from COVID-19 and improving the responsiveness of care; enabling rapid and effective identification and mitigation of COVID-19 transmission; and improving compliance with infection control policies.

CMS said the commission would also identify potential innovative approaches to using nursing home data for better coordination between federal, state and local entities.

For more information on long-term care facility and nursing home guidance, see CDC’s Preparing for COVID-19: Long-term Care Facilities, Nursing Homes and CMS’s Long-Term Care Nursing Homes Telehealth and Telemedicine Tool Kit.

**FDA Authorizes Emergency Use of Remdesivir:** The Food and Drug Administration issued Gilead Sciences an emergency use authorization for the investigational antiviral drug remdesivir to treat suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. The FDA previously allowed for study of the drug under clinical trials, as well as expanded access use for individual patients and through a multi-patient expanded access program coordinated by Gilead. The National Institutes of Health last week reported that a clinical trial provided preliminary indications that hospitalized patients with advanced COVID-19 and lung involvement who received remdesivir recovered faster than similar patients who received a placebo.

**AHA, Others Urge DOJ to Match CMS and OIG Relief from Certain Fraud and Abuse Sanctions:** The American Hospital Association, along with five other health organizations, urged Attorney General Bill Barr to join with the Department of Health and Human Services’ Centers for Medicare & Medicaid Services and its Office of the Inspector General in providing “relief from the technical requirements of the Federal fraud and abuse laws and the unnecessary risk they pose to hospitals during a declared public health crisis.”
CMS and IOG-HHS last month announced certain waivers and that they would forgo sanctions under the Stark Law and the Anti-Kickback Statute to enable hospitals and health systems to efficiently meet the demands of the public health emergency.

**Crisis Leadership Resource Now Available for Nurse Leaders:** The American Organization for Nursing Leadership unveiled a new resource to provide nurse leaders with practical tips and effective strategies for addressing challenges unique to a crisis.

The resource, which was made possible by a Johnson & Johnson Foundation educational grant, addresses the following for nurse leaders, nurses in clinical roles and other clinical leaders:

- Addressing moral distress;
- Grieving, coping and caring for oneself;
- Learning from culture shock;
- Channeling inner strength;
- Managing anxiety and stress; and
- Embracing mindfulness and self-compassion.

**Study: Ventilator Exchanges Could Save Lives During Pandemic:** A study published in Health Affairs proposes the federal government organize a national effort to exchange mechanical ventilators between states to take advantage of differences in demand, which the author estimates could save 7,070 to 28,197 lives based on a federal forecasting model and estimates of ventilator availability. The American Hospital Association last month joined with a group of U.S. hospitals and health systems and the Federal Emergency Management Agency to launch an online inventory of ventilators and associated supplies, called the Dynamic Ventilator Reserve, to aid in distributing available ventilators to critical areas in the fight against COVID-19.

**CDC Reports on Outcomes of Hospitalized COVID-19 Patients in Georgia:** A study of 305 hospitalized adult COVID-19 patients in Georgia found an overrepresentation of black patients, with over a quarter lacking known risk factors, according to a report released yesterday by the Centers for Disease Control and Prevention.

Among those studied, 83% were black, nearly 74% had high-risk conditions, and 61% were under age 65. Black patients, however, were not more likely to receive invasive mechanical ventilation, die during hospitalization or have worse outcomes than nonblack patients. The authors said public health officials should ensure that prevention activities prioritize communities and racial and ethnic groups most affected by COVID-19.

**CDC Tools Track Hospital Bed Occupancy, County-level COVID-19 Cases:** The Centers for Disease Control and Prevention launched the National Healthcare Safety Network COVID-19 Module Data Dashboard, which shows the share of inpatient and intensive care unit beds occupied by state as reported by acute care facilities participating in the Patient Impact and Hospital Capacity pathway of the NHSN COVID-19 module. As states move to reopen their economies, the Centers for Disease Control and Prevention has added county-level data on COVID-19 cases and deaths to its data tracker and webpage on U.S. cases.

**FDA Authorizes New COVID-19 Antibody Test’s Use, Accelerates Approval for Cancer Therapy:** The Food and Drug Administration last week issued an emergency use authorization for Abbott Laboratory’s SARS-CoV-2 IgG assay for the qualitative detection of COVID-19 antibodies. The FDA said that the test
may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with adaptive immune responses to the virus that causes COVID-19. The FDA also granted accelerated approval for a new dosing regimen for a cancer therapy that allows patients with certain cancers to continue treatment with fewer in-person visits. The approval was granted more than five months prior to the agency’s goal date.

**NIH Reports Promising Data on Remdesivir for Aiding COVID-19 Recovery:** A trial sponsored by the National Institutes of Health’s National Institute of Allergy and Infectious Diseases provided preliminary indications that hospitalized patients with advanced COVID-19 and lung involvement who received remdesivir recovered faster than similar patients who received a placebo. Remdesivir is an investigational, broad-spectrum antiviral treatment administered via daily infusion for 10 days. The randomized, controlled trial, which involved more than 1,000 patients from multiple sites around the world, found that patients who received remdesivir had a 31% faster recovery time, compared with those who received a placebo — 11 days for patients treated with remdesivir, compared with 15 days for those in the control group.

**Agencies Extend Employee Benefit Deadlines:** The departments of Labor and the Treasury are extending certain deadlines affecting employee benefit plan participants’ rights to health coverage, portability and continuation of coverage under COBRA, and to file claims or appeal denied claims. DOL’s Employee Benefits Security Administration also is extending the time for plan officials to furnish certain notices and disclosures under the Employee Retirement Income Security Act if they make a good faith effort to furnish the documents as soon as administratively practicable. For more on beneficiary rights and employer responsibilities under ERISA during the emergency, see the EBSA FAQ.

**Fed Expands Main Street Lending Program Eligibility, Scope:** The Federal Reserve Board expanded eligibility for the Main Street Lending Program to businesses with up to 15,000 employees or $5 billion in annual revenue. The program previously was limited to companies with up to 10,000 employees and $2.5 billion in revenue. The board also reduced the minimum loan size for two of the program’s loan options to $500,000 from $1 million.

Although nonprofit organizations are not currently eligible for the program, the board said it “recognizes the critical role that nonprofit organizations play throughout the economy and is evaluating a separate approach to meet their unique needs.” The American Hospital Association continues to urge Fed and Treasury officials to establish prompt guidance to ensure that nonprofit hospitals can access the loan facility. For the latest on the program, created by the Coronavirus Aid, Relief, and Economic Security Act, see today’s FAQ.

**New Tool Connects Hospitals with Compounders Who Can Provide Drugs in Shortage:** The Alliance for Pharmacy Compounding has launched a free tool for connecting hospitals with 503B outsourcing facilities, or alternatively, 503A sterile compounding pharmacies, which can supply shortage drugs to treat COVID-19. The hospital access page is password protected but hospitals can log on using info@iacprx.org as the user name, and compounding1 as the password. Hospital representatives will be asked to share basic contact information before they can access the page in question. Hospitals are also encouraged to help keep this information up to date via the same portal.

**CDC Issues COVID-19 Guidance for Providers Who Care for Breastfeeding Women:** The Centers for Disease Control and Prevention released guidance for health care providers who care for breastfeeding women and infants who receive breast milk, based on what is currently known about the virus that causes COVID-19 and the transmission of other viral respiratory pathogens. CDC plans to update the guidance as additional information becomes available.
NIH Launches Initiative to Speed Rapid COVID-19 Testing: The National Institutes of Health urged scientists and inventors with a rapid testing technology to compete for a share of $500 million in funding to develop accurate at-home and point-of-care diagnostic tests, with the goal to make millions of tests available per week by the end of summer and even more in time for the flu season.

“We need American tech experts, innovators and entrepreneurs to step up to one of the toughest challenges we’ve faced as a country, to help get us safely back to public spaces,” said Bruce Tromberg, director of the National Institute of Biomedical Imaging and Bioengineering. The challenge is part of a new NIH Rapid Acceleration of Diagnostics (RADx) initiative that will invest $1.5 billion in funding from the Paycheck Protection Program and Health Care Enhancement Act in early innovative testing technologies. RADx will expand an NIBIB Point-of-Care Technologies Research Network that supports innovators through technology hubs at Emory University/Georgia Institute of Technology; Johns Hopkins University; Northwestern University; University of Massachusetts Medical School; and the Consortia for Improving Medicine with Innovation & Technology at Harvard Medical School/Massachusetts General Hospital.

HHS Urged to Release 42 CFR Part 2 Rule: Members of the Partnership to Amend 42 CFR Part 2, including the American Hospital Association, Americas Health Insurance Plans, and the Blue Cross Blue Shield Association, last week urged the Department of Health and Human Services to issue a rule as soon as possible on the Part 2 provisions in the Coronavirus Aid, Relief, and Economic Safety Act. The CARES Act directs the agency to revise any pertinent regulations to implement the provisions, which ease Part 2 written consent requirements and align the regulations with HIPAA to make it easier for health care providers to coordinate care for patients with substance use disorders. “Given the longstanding nature of the issue, compounded with the potential for increase in SUDs during the current pandemic, it is more important than ever that the roadblocks to providing care for patients with SUDs are removed,” the coalition wrote. “We believe the recent changes to Part 2 in the CARES Act will greatly help in coordinating care for patients with SUDs.”

New IFDHE Resource Helps Hospitals Address Health Disparities During COVID-19 Crisis: The American Hospital Association’s Institute for Diversity and Health Equity released a new resource highlighting steps hospitals can and are taking to address disparities that arise during the fight against COVID-19. The resource includes examples of actions that can help ensure vulnerable populations receive equitable care. To learn more about hospital and health system efforts to advance equitable health and health care, visit IFDHE’s webpage.

FDA Issues Updated EUA, FAQ on Non-surgical Face Mask Use: The Food and Drug Administration has updated and reissued its April 18 emergency use authorization on face masks for the general public to clarify that non-surgical face masks are not intended for use by health care personnel as personal protective equipment, meaning they are not a substitute for respirator or surgical masks. For more information, see FDA’s FAQs on the EUA.

SAMHSA Awards Grants for Certified Community Behavioral Health Clinics: The Substance Abuse and Mental Health Services Administration awarded $450 million in grants, including $250 million in emergency COVID-19 funding, to expand access to mental health and substance use disorder treatment services through certified community behavioral health clinics.
“CCBHCs already perform a vital role of addressing in one location the complex needs of people with mental and substance use disorders,” said Assistant Secretary for Mental Health and Substance Use Elinore McCance-Katz, M.D. “The coronavirus pandemic substantially increases the need for these comprehensive services.” Congress last year extended CCBHC demonstration program through September 13.

**OSHA Issues COVID-19 Respirator Decontamination Guidance:** The Department of Labor’s Occupational Safety and Health Administration issued interim guidance on the reuse and decontamination of N95 and other filtering-facepiece respirators during the COVID-19 pandemic. The agency, via this enforcement memorandum, outlined a host of methods for decontaminating respirators, including vaporous hydrogen peroxide, ultraviolet germicidal irradiation and moist heat (e.g., using water heated in an oven). Alternately, if such methods are not available, OSHA said that microwave-generated steam and liquid hydrogen peroxide are suitable decontamination options. The guidance indicates that OSHA will, on a case-by-case basis, exercise enforcement discretion related to the reuse of decontaminated respirators consistent with the conditions outlined in this interim enforcement guidance.

**White House Outlines Testing Blueprint to Spur Nation’s Re-opening; CDC Updates Criteria:** The Trump administration put forward a series of guidelines for testing and rapid response programs in anticipation of reopening the nation’s economy. The effort is meant to be a partnership between federal, state, local and tribal governments and the private sector. The federal government will support state-based efforts by expanding the number of testing platforms, increasing testing and laboratory supplies and capacity, and enhancing sample collection.

As part of the effort, the Centers for Disease Control and Prevention updated its evaluation and laboratory testing criteria, stating that “increasing testing capacity will allow clinicians to consider COVID-19 testing for a wider group of symptomatic patients and persons without symptoms in certain situations.”

The following remain high priorities for COVID-19 testing:

- Hospitalized patients;
- Health care facility workers, workers in congregate living settings and first responders with symptoms;
- Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms; and
- Individuals identified through public health cluster and selected contact investigations.

A second, priority tier was established for individuals with symptoms for potential COVID-19 infection, along with those who are without symptoms who are prioritized by health departments and clinicians based on state and local plans.

**FDA Reiterates Need for Caution in Antimalarial Treatments’ Off-label Use for Treating COVID-19:** The Food and Drug Administration April 24 reminded health care providers of the need to closely monitor patients for serious and potentially life-threatening side effects of hydroxychloroquine and chloroquine when used off-label to treat COVID-19. In a Drug Safety Communication, FDA warned “adverse events were reported from the hospital and outpatient settings for treating or preventing COVID-19, and included QT interval prolongation, ventricular tachycardia and ventricular fibrillation, and in some cases death.” FDA encourages health care professionals and patients to report adverse reactions or quality problems with any human drugs to the agency's MedWatch Adverse Event Reporting program.
CMS Delays Maternal Opioid Misuse Model Start Date to July 2021: The Centers for Medicare & Medicaid Services recently announced a six-month delay in implementation of its Innovation Center Maternal Opioid Misuse (MOM) Model, due to COVID-19. Awardees now have until July 1, 2021 to screen and enroll beneficiaries in the MOM model, which seeks to address the sometimes-fragmented care of pregnant and postpartum Medicaid beneficiaries who have opioid-use disorders.

Postal Service Revises Mailing Standards for Certain Substances: The U.S. Postal Service released a temporary final rule updating its Hazardous, Restricted and Perishable Mail regulations for Category B infectious substances “to support the rapid deployment” of COVID-19 diagnostic tests through the mail during the public health emergency. In addition to updated packaging instructions, all shippers of COVID-19-related Infectious Substances Category B UN3373 must obtain authorization from the Postal Service prior to mailing, the rule states. “These measures are necessary to ensure that diagnostic kits potentially containing Category B Infectious Substances are packaged, marked and labelled properly to ensure safety and containment throughout transport.”

CMS Updates Infection Control Guidance for Home Health Agencies: The Centers for Medicare & Medicaid Services last week updated its infection control guidance for home health agencies participating in Medicare and Medicaid and for religious non-medical health care institutions participating in Medicare. The home health updates include additional information about CMS waivers and regulations; Centers for Disease and Control guidance for optimizing personal protective equipment; CDC return-to-work criteria for health care personnel with confirmed or suspected COVID-19; and recommendations for home health personnel who care for patients in assisted and independent living facilities.

SBA Now Accepting Paycheck Protection Program Loan Applications: The Small Business Administration and Department of the Treasury announced that SBA is now accepting and processing Paycheck Protection Program loan applications. President Trump signed the Paycheck Protection Program and Health Care Enhancement Act, which among other provisions, included an additional $310 billion for the Paycheck Protection Program.

CMS Reevaluates Accelerated Payment Program and Suspends Advance Payment Program: The Centers for Medicare & Medicaid Services April 26 announced it is reevaluating the amounts that will be paid under its Accelerated Payment Program and suspending its Advance Payment Program effective immediately. In late March, CMS had expanded the programs to all Medicare providers and suppliers meeting certain eligibility criteria. The programs are intended to provide necessary funds to providers when there is a disruption in claims submission and/or claims processing. The funds will be recouped by CMS after a certain timeframe, depending on the provider or supplier type. The agency reports that the programs have thus far provided more than $100 billion to providers and suppliers during the COVID-19 public health emergency. Specifically, CMS approved more than 21,000 applications totaling $59.6 billion in payments to Part A providers, including hospitals. CMS approved almost 24,000 applications totaling $40.4 billion in payments for Part B suppliers, including doctors and other practitioners.

Beginning April 26, CMS will not accept any new applications for the Advance Payment Program, and the agency will be reevaluating all pending and new applications for Accelerated Payments. CMS has previously referred to “accelerated” payments in reference to inpatient prospective payment system hospitals, children’s hospitals, cancer hospitals and critical access hospitals and “advance” payments in reference to all other providers and suppliers. CMS states that the reevaluation is in light of the payments made through the Provider Relief Fund distributed by the Department of Health and Human Services. The American Hospital Association had previously urged the agency to make a number of improvements to the
accelerated and advance payment programs, including more flexible repayment terms and elimination or substantial reduction in the interest rate.

**HHS Launches COVID-19 Uninsured Program Portal:** Health care providers are eligible for reimbursement from the federal government for COVID-19 testing, treatment and related services provided to the uninsured. Providers, including hospitals and health systems, can register to participate with the Health Resources and Services Administration. This coverage of the uninsured was authorized and funded through the Families First Coronavirus Response Act and the Coronavirus Aid, Relief and Economic Security Act. More information regarding the program, including how to register, can be found here.

**CDC Unveils Surge-capacity Tool for Hospital Administrators, Public Health Officials:** The Centers for Disease Control and Prevention released a new tool for estimating surges in demand for hospital-based services related to COVID-19. CDC said the spreadsheet-based tool can help hospital administrators and public health officials “produce estimates of the number of COVID-19 patients that need to be hospitalized, the number requiring ICU care, and the number requiring ventilator support.”

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**State Issues**

**Pennsylvania**

**Legislative**

**Governor Wolf Vetoes Telemedicine Measure, Voicing Objections to Abortion Language**
Legislation introduced to regulate the use of telemedicine services and require health insurers to reimburse health care providers delivering eligible telehealth services, was vetoed April 29 by Governor Tom Wolf.

The proposal, Senate Bill 857, also prohibited the administration of abortion-related services by referencing the list established by the U.S. Food and Drug Administration—the Risk Evaluation and Mitigation Strategies (REMS) list. One of the listed drugs, mifepristone, is an early-term abortion medication which can only be dispensed under the supervision of a physician. Governor Wolf specifically referenced the importance of the decision-making process between physician and patient in his Veto Message.

**Pharmacy Gag Clause Bill Clears Senate Committee**
The Senate Health and Human Services Committee voted unanimously to advance House Bill 943, legislation that prohibits Pharmacy Benefits Managers (PBM) from including “gag clauses” in pharmacy network contracts that would prohibit pharmacies from sharing cost data regarding prescription drugs to insured individuals.

Prior to voting on the bill, the committee approved an amendment to remove the authorization that pharmacies could also share information regarding contract information without being penalized by a PBM or Pharmacy Services Administration Organization.

House Bill 943 was referred to the Senate Appropriations Committee for further consideration.
House Insurance Committee Approves ACA, Mental Health Reporting Proposals

The House Insurance Committee voted April 27 to approve several measures addressing the Affordable Care Act (ACA) and federal mental health parity laws:

- **House Bill 469** – Ensures that health insurance policies in Pennsylvania provide coverage for the categories of essential health benefits that are contained in the federal law;
- **House Bill 470** – Prohibits insurers from creating arbitrary annual/lifetime health insurance coverage limits;
- **House Bill 471** – Prohibits insurers from denying or excluding coverage based on pre-existing conditions; and
- **House Bill 913** – Provides parents, not employers, the option of retaining health insurance coverage for their children up to the age of 26.

- **House Bill 1439** – Provides for mental health parity and access to coverage for addiction treatment; and
- **House Bill 1696** – Requires an insurer to annually file with the Insurance Department such information as required by the Department to determine the insurer’s compliance with the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008.

The House of Representatives is slated to vote on House Bills 1439 and 1696 during the week of May 4.

Hospital Perspective Focusses on Safety in Testimony at Joint Senate Committee Hearing, Reopening of Pennsylvania

Yesterday, via teleconference, the Senate Health and Human Services Committee held a joint hearing with the Senate Local Government Committee on the reopening of the commonwealth after weeks of a statewide stay at home order that began on April 1. The committee heard from members of the Wolf Administration, including the Department of Community and Economic Development, the Department of Health, Pennsylvania Emergency Management Agency as well as local government officials, and representatives from the health care community.

The Hospital & Healthsystem Association of Pennsylvania presented a statement on what reopening means for the commonwealth’s hospitals and answered questions from committee members. Robert Shipp, HAP’s vice president for quality and population health, highlighted that patient, staff, and visitor safety is the top priority of hospitals as they assess their individual approach to resuming scheduled services.

HAP noted in its testimony that infection control professionals and other members of the hospital team will be taking every precaution to protect patients and health care workers. These procedures will begin when patients enter the facility—with efforts to direct people to specific entrances, don masks, and create safe social distancing—and it will include strict disinfecting and infection control processes, from door pulls to elevator buttons. Since March 19, hospitals and health systems have significantly slowed or stopped medically necessary surgeries and non-emergent procedures in order to mitigate the spread of COVID-19 and preserve limited health care resources. As a result, needed patient care was put on hold. Some examples of these procedures are heart catheterizations, joint replacements to improve ambulation, decrease pain and prevent falls, and colonoscopies which prevent colorectal cancer and save lives.

It was reported during the hearing that the resumption of scheduled surgeries likely will lead to gradual volume increases in a staggered fashion across the commonwealth due to the differences in how the virus has transmitted in the various regions.
Last week, the Pennsylvania Department of Health advised that hospitals may begin to allow scheduled admissions and perform surgeries and procedures if the hospital or ambulatory surgery center makes an affirmative decision that it is able to do so without jeopardizing the safety of patients and staff or the hospital's ability to respond to the COVID-19 emergency.

Regulatory

**Pennsylvania Department of Health Recent Health Advisory and Updates**

The Pennsylvania Department of Health (DOH) has issued a health advisory and two new updates. These notifications sent out to the Health Alert Network contain new or updated guidance for the following conditions:

- Advisory 502—Discontinuation of Transmission-Based Precautions for Patients with COVID-19
- Update 501—Return to Work for Healthcare Personnel with Confirmed or Suspected COVID-19
- Update 500—Interim Guidelines for Collecting Clinical Specimens for COVID-19 Testing

Additionally, the Hospital & Healthsystem Association of Pennsylvania released a Resuming Scheduled Surgery and Procedures Toolkit which can be accessed online.

**Why this matters:** The PA Health Alert Network (PA-HAN) is the communication network between the DOH state and local health agencies, health care providers, hospitals, and emergency management officials. These advisories reflect up-to-date educational and reference materials to address the changing regulatory and clinical landscape during the COVID-19 pandemic.

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**State Issues**

**West Virginia**

Regulatory

**Governor Justice Announces Plan for Reopening West Virginia—WV Strong, The Comeback**

Governor Jim Justice announced April 27 his administration’s plan for reopening the state—WV Strong, The Comeback. Justice was joined by several members of his cabinet in sharing the news, which included an overview of COVID-19 statistics and how the state has fared during the crisis. Justice has closely coordinated with legislative leaders on this and other reopening issues.

Criteria for reopening the state includes three consecutive days of where the statewide cumulative infection rate is below three percent. **NOTE: The state met this threshold and has moved to the next phase of reopening – phase two.**

The reopening phases include:

- Week one: Hospital reopenings and daycare testing;
- Week two: Monday, May 4—small businesses of less than 10 can go back. Hair salons, etc. can go back while waiting outside for appointments, etc. Outdoor dining permitted at restaurants. Churches and funerals permitted with limited gathering sizes. Physical distancing and masks required at all;
Week three through six: Office/government buildings, specialty retail stores, parks, gyms, dine-in restaurants, hotels, casinos, spas, and remaining other businesses; and
There is currently no timeline for reopening nursing home visitation, movies, concerts, sporting events or any gathering of more than 25 people.

Updates to the plan will be announced a week in advance of each phase. Also included in the plan:

- Testing in the state has expanded, particularly for nursing homes and at-risk populations. Experts continue to monitor the daily infection rate, which has dropped from over four percent to a rate of 2.47 percent;
- Hospital surge capacity was increased while hospitals restart;
- Increasing supply of PPE and increasing contact tracing for positive cases;
- Encourage the continued practice of physical distancing; wear face coverings in public and where distancing is difficult; follow statewide stay at home order until it is lifted; follow county health rules and; telework when possible;
- Establish conditions for a slowed, stop or reversal of reopenings: an unexpected increase in hospitalizations from the virus, a significant community transmission outbreak, or the cumulative percentage of positive tests surges above three percent;
- County by county and hotspot evaluations will drive decisions on slowing down or stopping reopenings;
- Guidance for each business sector will be released at least a week in advance; and
- Limitations on size of gatherings will remain in place. All info to be reported online at virus site.

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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