Federal Issues

Legislative

Washington Focuses on Coronavirus Response
Emergency measures related to fighting the coronavirus (COVID-19) dominated the landscape in Washington last week, with Congress continuing hearings and passing an emergency appropriations package, while CMS announced a spate of actions aimed at addressing the spread of the virus in the United States.

Emergency spending bill sails: On Wednesday, the House overwhelmingly passed by a vote of 415-2 an $8.3 billion emergency appropriations package focused primarily on responsive and protective measures. The Senate followed suit on Thursday, passing the bill by a vote of 96-1 and President Trump signed it on Friday. The legislation:

- Allocates nearly $7.8 billion to federal, state and local agencies and stakeholders that are responding to the crisis.
- Provides Medicare providers roughly $500 million to administer telehealth services for elderly patients, who are particularly vulnerable to this particular strain of infectious disease.

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• Directs the Secretary to use existing authority to ensure that vaccines, therapeutics and diagnostics will be affordable in the commercial market.

Meanwhile, two committees continued examination of the outbreak:
• The Senate HELP Committee held a hearing in which Members heard from Administration officials from the Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), Department of Health and Human Services (HHS), and U.S. Food and Drug Administration (FDA).
• The House Committee on Science, Space & Technology also held a hearing, “Coronaviruses: Understanding the Spread of Infectious Diseases and Mobilizing Innovation Solutions,” to hear from clinical and academic public health experts.

Other actions: The CDC also revised its guidelines last week regarding testing for the coronavirus, expanding the recommendations to a wider group of symptomatic patients. The Administration is also reportedly considering using a national disaster program to pay providers for the care of uninsured people who have the coronavirus.

Industry response: On Thursday, AHIP’s Board of Directors released a statement on actions being taken by insurers to address COVID-19 and BCBSA has developed a resource for regular updates.

SCOTUS Accepts ACA Appeal for Next Term
The Supreme Court on March 2, 2020, announced it will hear Texas v. United States, the third major challenge to the Affordable Care Act (ACA) since its implementation in March 2010. The lawsuit was originally filed by 20 Republican attorneys general and governors, with support from the Trump Administration, and was opposed by 20 Democratic states and the U.S. House of Representatives.

Why it matters: At the heart of the case are questions about the constitutionality of the individual mandate after Congress zeroed out the mandate’s penalty in 2017, and, if unconstitutional, what parts, if any, of the ACA should remain. The ruling could create significant uncertainty in the individual and small group markets, as well as for Medicaid expansion.

The timing: Should the Supreme Court schedule oral arguments for this fall, a decision would not be expected until late spring or early summer 2021. The Democratic AGs’ brief will be due April 16, and the
Republican AGs’ brief as well as the Department of Justice brief will be due May 18, unless an extension is granted. Amicus briefs in support of the law will be due on April 23.

**Capito, Manchin Reintroduce Bill to Amend 42 CFR Part 2**

On Tuesday, Sens. Shelley Moore Capito (R-WV) and Joe Manchin (D-WV) reintroduced the Protecting Jessica Grubb’s Legacy Act (S.3374) legislation that would modernize privacy regulations affecting the disclosure of substance use disorder treatments records to better enable health care providers to coordinate care.

The bipartisan bill would more closely align 42 CFR Part 2 with HIPAA regulations and strengthen protections against discrimination, while allowing patients to opt-in to share their addiction records in a variety of coordinated care settings.

*Why it matters:* The legislation would help fight opioid addiction by addressing outdated regulations [42 CFR Part 2 (Part 2)] that set requirements limiting the use and disclosure of patients’ substance use records. The restrictions run counter to new, innovative delivery models that rely on providers’ ability to share health information to effectively and safely coordinate high quality treatments.

*Industry position:* AHIP, BCBSA, the AHA, and 50 other healthcare organizations support The Partnership to Amend 42 CFR Part 2, which advocates for fully integrated care for people with substance use disorder (SUD) by allowing SUD providers to share records for the purposes of health care treatment, payment, and operations. The Partnership released a statement in support of the legislation.

**Drug Shortages Bill Introduced**

A bipartisan group of U.S. House members last week introduced the Preventing Drug Shortages Act (H.R. 6080). The bill would strengthen drug shortage reporting requirements under the Food and Drug Administration Safety and Innovation Act of 2012 to include manufacturers of active pharmaceutical ingredients and information such as the cause, extent and expected duration of shortages. It also would require manufacturers to implement risk management plans.

*Why it matters:* Drug shortages have been on the rise for several years, with an estimated 210 drugs currently at risk or not readily available for U.S. hospitals, according to the national database maintained by the American Society of Health System Pharmacists (ASHP). Furthermore, as the United States takes steps in response to the outbreak of COVID-19, concerns with the integrity of the drug supply chain and the potential impact on downstream drug shortages have surfaced.

Drug shortages impact every single segment of the healthcare ecosystem and are a major driver of skyrocketing costs, contributing to half a billion dollars in increased healthcare expenditures annually. Drug shortages also result in increased potential for adverse events and increased costs to the healthcare system, such as increased hospital days, due to the unavailability of a critical medication.

Congress has made major strides in helping to address drug shortages in the past by enacting the Food and Drug Administration Safety and Innovation Act (FDASIA) Title X reporting requirements, the track and trace requirements of the Drug Quality and Safety Act, the Competitive Generics Therapy pathway under
the FDA Reauthorization Act of 2017 (FDARA), and others. These bipartisan Congressional actions have made a significant contribution to the effort to reduce the impact of drug shortages, but more needs to be done to help eliminate drug shortages once and for all.

**Hospital Association position:** “The Preventing Drug Shortages Act builds upon the prior work of Congress to provide additional authority to the FDA to help mitigate drug shortages to ensure a stable supply of medications critical for patient care,” The American Hospital Association and other 12 national organizations said in a letter of support for the bill.

Last week, the AHA and others urged the Senate Health, Education, Labor and Pensions Committee to quickly advance the Mitigating Emergency Drug Shortages (MEDS) Act (S.2723), bipartisan legislation that also would strengthen drug shortage reporting requirements and include manufacturers of active pharmaceutical ingredients, among other provisions.

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**United PA House Delegation Urges CMS to Rethink Medicaid Regulation**

U.S. Congressmen Brendan Boyle (D, PA–02) and Mike Kelly (R, PA–16) spearheaded a letter—signed by all 18 members of the Pennsylvania U.S. House delegation—recognizing the Administration’s efforts to foster accountability within the Medicaid program but cautioning that the Medicaid Fiscal Accountability Regulation (MFAR) “puts into jeopardy the care and services the Commonwealth of Pennsylvania provides to the most vulnerable and sick in our communities.”

As previously reported, the MFAR proposal, issued by the Centers for Medicare & Medicaid Services (CMS) during November 2019, which would dramatically reshape state Medicaid program financing and supplemental payments for providers, ultimately impacting access to care for more than 2.8 million Pennsylvanians who rely on Medicaid for quality coverage.

The delegation letter, addressed to CMS Administrator Seema Verma, calls for the Trump Administration to “continue to engage and work with relevant stakeholders” and urges “fundamental rethinking of the MFAR proposal… recognizing the jeopardy it places on our rural and urban safety net hospital systems, providers, children, and low-income Medicaid beneficiaries.” The delegation letter cited support for efforts to bring more transparency and fiscal accountability to the health care system.

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**Federal Issues**

**Regulatory**

**Coronavirus Updates from CDC and CMS**

The Centers for Disease Control and Prevention last week updated its guidance for risk assessment and public health management of health care personnel with potential exposure to patients with novel coronavirus (COVID-19).

In the setting of community transmission, CDC says facilities should shift emphasis to more routine practices, which include asking health care personnel to “report recognized exposures, regularly monitor themselves for fever and symptoms of respiratory infection and not report to work when ill.”
In addition, CDC says facilities could consider allowing asymptomatic health care personnel who have had exposure to a COVID-19 patient to continue to work after consultation with their occupational health program.

The Centers for Medicare & Medicaid Services has provided several actions to help healthcare providers. Below is a list of actions to date:

- **March 5, 2020:** CMS issued a second Healthcare Common Procedure Coding System (HCPCS) code for certain COVID-19 laboratory tests, in addition to three fact sheets about coverage and benefits for medical services related to COVID-19 for CMS programs.
- **March 4, 2020:** CMS issued a call to action to healthcare providers nationwide and offered important guidance to help State Survey Agencies and Accrediting Organizations prioritize their inspections of healthcare. Until further notice, state agencies and accrediting organizations inspecting nursing homes and hospitals will focus “exclusively on issues related to infection control and other serious health and safety threats, like allegations of abuse.”
- **February 13, 2020:** CMS issued a new HCPCS code for providers and laboratories to test patients for COVID-19.
- **February 6, 2020:** CMS issued a memo to help the nation’s healthcare facilities take critical steps to prepare for COVID-19.
- **February 6, 2020:** CMS gave CLIA-certified laboratories information about how they can test for SARS-CoV-2.
- **February 6, 2020:** CMS issued a memo to help the nation’s healthcare facilities take critical steps to prepare for COVID-19.

CMS also issued frequently asked questions and answers (FAQs) for healthcare providers regarding Medicare payment for laboratory tests and other services related to COVID-19. The agency is receiving questions from providers and created this document to be transparent and share answers to some of the most common questions. Included in the FAQs is:
- Guidance on how to bill and receive payment for testing patients at risk of COVID-19;
- Details of Medicare’s payment policies for laboratory and diagnostic services, drugs and vaccines under Medicare Part B, ambulance services, and other medical services delivered by physicians, hospitals, and facilities accepting government resources; and
- Information on billing for telehealth or in-home provider services.

**Why it matters:** The federal agencies’ actions in response to the COVID-19 virus are helping providers to prepare for and respond to the COVID-19 outbreak. Hospitals and health systems across the country are working around-the-clock on this issue. Some are already caring for patients with COVID-19, and every hospital and health system is preparing to do so. They also are working with a number of health care system partners and coalitions in their community on these efforts. These federal policies will help to make sure hospitals and health systems have the resources they need to respond, treat patients and protect their teams from exposure.

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**CMS Issues State Guidance on CHIP Behavioral Health Coverage**

The Centers for Medicare & Medicaid Services issued guidance to states implementing Section 5022 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018, which requires all states with separate Children’s Health Insurance Programs to
cover specific behavioral health-related screening and preventive services for children and pregnant women.

The guidance includes a template for submitting CHIP state plan amendments to comply with the section, including requirements to provide these services in a culturally and linguistically appropriate manner and facilitate use of appropriate screening and assessment tools.

**Why it matters:** Mental health is key to overall health and plays a critical role in the well-being of children and pregnant women. There are unique vulnerabilities and developmental implications when it comes to mental health and substance use disorder conditions in children and pregnant women. Mental health disorders usually first arise in childhood, adolescence or early adulthood. As many as one in six U.S. children between the ages of 6 and 17 has a treatable mental health disorder.

In 2018, an estimated 21.2 million people aged 12 or older needed substance use treatment. About 1 in 26 adolescents aged 12 to 17 (3.8 percent), and about one in seven young adults aged 18 to 25 (15.3 percent) needed treatment.

Several common mental health conditions impact Medicaid and CHIP children at higher rates than the general child population including conduct disorder, anxiety disorder, depression, autism spectrum disorder, and attention deficit disorder.

With respect to pregnant women, approximately 40 percent experience psychological difficulties during or after pregnancy with 10 to 15 percent being diagnosed with a mental illness.

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**State Issues**

**Pennsylvania**

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**Autism Spectrum Disorders Coverage—Maximum Benefit Adjustment Increase**

Under Pennsylvania Law, after December 30, 2011, the Insurance Commissioner is required to publish in the *Pennsylvania Bulletin*, on or before April 1 of each calendar year, an adjustment to the maximum benefit equal to the change in the United States Department of Labor Consumer Price Index for All Urban Consumers (CPI-U) in the preceding year. The published adjusted maximum benefit is then applicable to the following calendar years to health insurance policies issued or renewed in those calendar years. The CPI-U change for the year preceding December 30, 2019, was an increase of 2.3 percent. Accordingly, the maximum benefit, previously adjusted to $41,271 per year, is hereby adjusted to $42,220 for policies issued or renewed in calendar year 2021. Notice 2020-02 was published in the March 7 *Pennsylvania Bulletin*.

**PA’s First Presumptive Positive Cases of COVID-19 Announced; Governor Declares Emergency Disaster Declaration**

On Friday, March 6, Pennsylvania Governor Tom Wolf held a press conference to announce the commonwealth’s first presumptive positive cases of the coronavirus disease 2019 (COVID-19). Governor Wolf also signed a COVID-19 disaster declaration to support the state’s response.
The disaster declaration is an additional way the state can prepare for and respond to suspected or confirmed cases in the commonwealth and to implement measures to mitigate the spread of COVID-19. Under the disaster declaration, the governor authorized the Pennsylvania Emergency Management Agency Director or his designee to assume command and control of all statewide emergency operations and authorize and direct that all commonwealth departments and agencies use all available resources and personnel as is deemed necessary to cope with this emergency situation.

The disaster declaration follows the Department of Health’s activation of its Department Operations Center at the Pennsylvania Emergency Management Agency’s headquarters to conduct public health and medical coordination for COVID-19 throughout the commonwealth.

Why it matters: COVID-19 remains a new disease and the situation changes day to day. The most accurate and timely resources about COVID-19—including guidance for health care facilities and staff—is available at DOH’s and the Centers for Disease Control and Prevention’s webpages.

Opioid Treatment Agreement Temporary Regulations Published

Background: Act 112 of 2019 requires providers to take several additional steps before issuing a prescription for an opioid in certain treatment situations. Specifically, the Act’s requirements kick in before a prescriber can issue a patient the first prescription in a single course of treatment for chronic pain with a controlled substance containing an opioid.

Among the new requirements, the prescriber must:
- Determine whether an individual has taken or is currently taking a prescription drug to treat a substance use disorder;
- Have a discussion with the patient about the risks of addiction, and additional risks if the patient suffers from a mental health condition or substance use disorder;
- Present non-opioid treatment options available; and
- Discuss the dangers of taking a controlled substance containing an opioid with benzodiazepines, alcohol, or other depressants.

The prescriber must review with the patient, and both must sign, a treatment agreement containing a number of required elements, including the patient’s consent to targeted urine drug testing if medically necessary. The prescriber must obtain written consent from the patient for the prescription, and record the consent on the treatment agreement. The treatment agreement must be maintained in the patient’s medical record.

The law exempts from these requirements medical emergencies, management of pain associated with cancer, and use in palliative or hospice care. Violations of the law may result in sanctions to the Prescriber’s license in accordance with the applicable professional practice act. The Act was effective immediately, and mandates that the Pennsylvania Department of Health issue regulations within 90 days of the Act’s enactment.
Stakeholders had the opportunity to review and comment on the proposed temporary regulations prior to the publication. Comments received were taken into consideration and were applied appropriately to modify the temporary regulations.

**Key provisions of the regulations**

DOH clarified the following in the temporary regulations:

- “Individual” defined as a natural person who is at least 18 years of age
- “Prescription” or “prescription order” is defined as a written, oral or electronic order for a controlled substance, other drug or medication, or device for medication which is dispensed to or for an ultimate user. This does not include an order for a controlled substance, other drug or medication, or device for medication which is dispensed for immediate administration to the ultimate user
- Exception to urine testing—DOH will allow other drug testing only when a patient, out of medical necessity, cannot produce urine for drug testing
- Details regarding the termination of Opioid Treatment Agreement
- Provision regarding DOH’s role in enforcement, which is delegated to the appropriate licensing boards. DOH will refer any known complaints to those boards

The temporary regulations, along with answers to frequently asked questions, are available at the DOH [website](#).

**Why it matters:** While many providers have already been taking steps similar to those now required by the Act for quite some time, it is important to ensure that existing processes, procedures, and documents comply with the Act’s requirements and new temporary regulations.

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**State Issues**

**West Virginia**

**Legislative**

**West Virginia 2020 Legislative Session Ends, Passing Several Bills Impacting Highmark**

The West Virginia Legislature adjourned Saturday at midnight, bringing to a close their 2020 legislative session. The last 60 days culminated in the passage of myriad health care-related measures that were new to the legislative landscape, as well as several others that had been reintroduced from previous legislative sessions – with the focus addressing health care provider reimbursement and some consumer protections.

Highlighted below are the 2020 bills impacting Highmark West Virginia. We will share links to final bill language in next week’s edition of the Weekly Capitol Hill Report. They are pending signing by Governor Jim Justice, if not noted:

**House Bill 4003, Telehealth Requirements**—This measure establishes coverage parity for telehealth services and in-person visits to a health care provider. House Bill 4003 does not require payment parity to a provider for services delivered via telehealth.

**House Bill 4061, Health Benefit Plan Network Access and Adequacy Act / Assignment of Dental Benefits**—The bill is a NAIC model that proposes similar network adequacy reports and rules on health
plans that are currently required of Medicaid MCOs and HMOs. The measure is an initiative of the Office of the Insurance Commissioner.

**House Bill 4543, Insulin Cost Cap**—In the final days of session, advocates for House Bill 4543 failed in their attempts to maintain a $25 co-pay for insulin. The Senate, which initially planned not to take up the bill, reconsidered and successfully added language that increased the monthly insulin co-pay to $100 and removed a provision to freeze the price of insulin at 2006 levels.

**Senate Bill 787, Pharmacists Credentialing and Payment for Care**—This measure requires commercial health insurers to credential and reimburse pharmacists for all services rendered to patients that are permitted under their scope of practice as a “health” benefit versus a pharmacy benefit.

Prior to final passage, Senate Bill 787 was amended to remove requirements that it apply to Medicaid.

**House Bill 4359, Insurer Filing Fees**—Governor Jim Justice signed House Bill 4359 on Saturday, March 7. The new law, proposed by the Office of the Insurance Commissioner (OIC) will standardize the filing fee for all matters at the Insurance Commissioner at a level of $100, regardless of the number of filings that are made simultaneously.

**House Bill 4361, Insurance Law Violations**—Also proposed by the OIC, this bill addresses standards for insurance plan fraud protections for all lines of coverage.

**House Bill 4422, Patient Brokering**—House Bill 4422 will establish anti-patient brokering standards and permit enforcement against unscrupulous substance abuse treatment programs that have popped up all around the state.

**Senate Bill 291, Mental Health Parity Requirements**—Senate Bill 291 passed both chambers Saturday evening.

- The bill addresses mental health coverage provided by the Public Employees Insurance Agency (PEIA) and commercial health plans and their perceived limitations as compared to physical health benefits.

**Senate Bill 544, Immunization Administration by Pharmacists and Interns**—Governor Jim Justice signed Senate Bill 544 on Thursday, March 5. The new law reflects the agreement between the Boards of Pharmacy, Medicine and Osteopathy to expand the scope of immunization administration authority. The new law is effective 90 days after February 18.

**Senate Bill 689, Pharmaceutical Transparency and Reporting Act**—Senate Bill 689 requires pharmaceutical manufacturers and health plans to disclose and report a wide variety of data on prescription drug costs and utilization. AARP was the primary advocate for Senate Bill 689. Gov. Jim Justice is expected to sign the measure.

**Other Bills Headed to Governor Justice for Consideration**

- **Senate Bill 562, Expungement of Criminal Convictions**—Expunges certain criminal convictions
- **Senate Bill 719, Health Care Provider Tax**—Senate Bill 719 imposes a health care-related provider tax on certain health care organizations. More specifically, the measure adjusts the MCO tax first enacted in 2018 to meet current CMS requirements. It will pass through $50 million from
Medicaid MCOs to generate approximately and additional $250 million in matched revenues for the Medicaid program.

- **Senate Bill 748, Palliative Care**—Increases awareness of palliative care services.
- **Senate Bill 797, Hospital Police Officers**—Authorizes governing boards of public and private hospitals to employ hospital police officers.
- **Senate Bill 846, Notification of Facility Closure**—Requires hospitals to publish notification prior to facility closure regarding access to patient medical records.
- **House Bill 4198, Access to Contraceptives**—Permits an individual to obtain a 12-month supply of contraceptive drugs.

The Pennsylvania General Assembly is in recess March 9-13.

The Delaware Legislature returns to session March 17.

The West Virginia Legislature is in session January 8 - March 7.

**Congress**
The U.S. House and Senate are in session March 9-12. The U.S. Senate is in session March 13.

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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