Federal Issues

Legislative

House Passes Affordable Care Act Enhancement Legislation
The U.S. House of Representatives voted, almost entirely along party lines, to pass the Patient Protection and Affordable Care Enhancement Act (H.R. 1425) by a vote of 234-179.

Highlights of the bill include:
- Expanded eligibility for premium tax credits beyond 400% of the federal poverty line and increases the size of tax credits for all income brackets;
- Creating a national reinsurance program;
- Offering funding for states to establish their own State-Based Marketplaces;
- Renewing the Affordable Care Act’s (ACA) expanded federal matching for states that adopt Medicaid expansion;
- Allowing for the direct negotiation of drug prices under Medicare;
- Extending Medicaid and the Children’s Health Insurance Program (CHIP) coverage to new mothers from the current 60 days post-partum to one year; and

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• Ensuring that Medicaid and CHIP beneficiaries receive a full 12 months of coverage once enrolled, among others.

AHIP & BCBSA Send Recommendations on COVID-19 Response to Congress

AHIP and BCBSA sent a letter to Congressional leaders outlining further legislative recommendations to help Americans maintain their health coverage, keep it affordable and stable, and ensure access to care as COVID-19 continues to affect the country.

Recommendations include:
• Support businesses in continuing to provide health coverage to their employees through temporary subsidies, direct financial assistance, and full subsidization of COBRA;
• Make coverage less costly for those who buy coverage in the individual market exchanges;
• Ensure access to widespread testing for COVID-19 with federal funding;
• Strengthen support for Seniors and People with Disabilities through stabilization of risk scores and MA and Part D medical loss ratios (MLR);
• Support states through an increase in the Federal Medical Assistance Percentage (FMAP);
• Support patient access to a safe, effective, and affordable vaccine; and
• Delay regulations to free up capacity to respond to the COVID-19 crisis, among others.

The letter also provides examples of decisive actions that health insurance providers are taking to help patients and curb the spread of the virus.

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Senate Republicans Introduce Price Transparency Legislation

Senate Republicans introduced the Health Care PRICE Transparency Act (S. 4106), codifying the Administration’s published transparency rules that reflect the Improving Price and Quality Transparency in American Healthcare Executive Order.

Background
- Under a final rule issued during November 2019, hospitals are required to disclose the standard charges, including payor-specific negotiated rates, for all services beginning January 1, 2021.
  - The American Hospital Association (AHA) and other hospital associations filed suit and argued that HHS lacked the statutory authority to require public disclosure of individually negotiated rates between commercial insurers and hospitals.
  - A federal judge ruled against this lawsuit, however, the AHA plans to appeal the court’s decision and seek an expedited review.
- In separate rulemaking, CMS has proposed health plans also release information on negotiated rates and provide cost-sharing information to members. This rule is expected to be finalized later this year.

The Health Care PRICE Transparency Act requires health insurance providers to:
- Provide consumers real-time, personalized access to cost-sharing information—including an estimate of their cost-sharing liability for all covered healthcare items and services;
- Make cost-sharing information available online, and in paper form at the beneficiaries’ request; and
- Disclose on a public website negotiated rates for in-network providers and allowed amounts paid for out-of-network providers.

S.4106 would also require hospitals to provide patients with information on the standard charges for the items and services they provide, and to make those charges publicly available.

Insurer & Hospital Perspective: AHIP, BCBSA, the AHA, and a number of health care organizations continue to encourage Congress and the Administration to implement meaningful transparency for consumers while protecting proprietary price information.

MMA Partners Urge Congress to Increase Medicaid Funding Amid COVID-19

Nearly 40 partners in the Modern Medicaid Alliance (MMA) sent a letter to Congressional leadership urging immediate action to strengthen the Medicaid program in pending and future COVID-19 relief packages.

Why this matters: The letter calls on Congress to enhance federal financing for Medicaid by increasing states’ Federal Medical Assistance Percentage (FMAP) by at least 12 percentage points, consistent with the request made by the bipartisan National Governors Association.

Federal Issues

Regulatory
SAMHSA Finalizes Changes to the Disclosure of SUD Treatment Records
The Substance Abuse and Mental Health Services Administration (SAMHSA) released a final rule amending federal regulations regarding disclosure of patient information for individuals seeking treatment for substance use disorders. The changes to the regulations, known as 42 CFR Part 2, would reduce the burden and delay associated with accessing certain recovery services and add declared disasters to the list of exceptions.

The new rule advances the integration of healthcare for individuals with substance use disorders while maintaining critical privacy and confidentiality protections. Under Part 2, a federally assisted substance use disorder program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. Health care providers, with patients' consent, will be able to more easily conduct such activities as quality improvement, claims management, patient safety, training, and program integrity efforts.

What has not changed under the new Part 2 rule: The revised rule does not alter the basic framework for confidentiality protection of substance use disorder patient records. Part 2 continues to prohibit law enforcement’s use of SUD patient records in criminal prosecutions against patients, absent a court order. Part 2 also continues to restrict the disclosure of SUD treatment records without patient consent, other than as statutorily authorized in the context of a bona fide medical emergency; or for the purpose of scientific research, audit, or program evaluation; or based on an appropriate court order.

What has changed under the new Part 2 rule: The revised rule modifies several major sections of Part 2, among the key provisions are:
- Treatment records created by non-Part 2 providers based on their own patient encounter(s) are explicitly not covered by Part 2;
- An SUD patient may consent to disclosure of the patient’s Part 2 treatment records to an entity (e.g., the Social Security Administration), without naming a specific person as the recipient for the disclosure; and
- Disclosures for the purpose of “payment and health care operations” are permitted with written consent, in connection with an illustrative list of 18 activities that constitute payment and health care operations now specified under the regulatory provision, including care coordination and case management activities.

Why this matters:
- The adoption of this revised rule represents a historic step in expanding care coordination and quality. This reform will help make it easier for Americans to discuss substance use disorders with their doctors, seek treatment, while lifting burdens on providers and maintaining important privacy protections.
- Will strengthen the nation’s efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders.
- Although well-intentioned, the non-disclosure of critical, lifesaving information the previous rule permitted is itself stigmatizing.
- This serves as an important milestone in further aligning 42 CFR Part 2 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.
New Provider Relief Fund to Support Safety-Net Hospitals, Rural Providers, and Providers from Small Metro Areas

In a press release on Friday, the U.S. Department of Health and Human Services (HHS) announced new distributions through the $175 billion Provider Relief Fund, including $3 billion in additional funding for safety net hospitals and $1 billion for rural and small city providers.

Safety-Net Hospital Distribution—Using a revised qualification criteria, HHS will provide $3 billion to 215 safety net hospitals that had not been eligible for the $10 billion safety net distribution announced in June. The Provider Relief Fund has now provided a total of $12.8 billion to 959 hospitals that serve a disproportionate number of Medicaid patients or provide large amounts of uncompensated care, and operate on incredibly thin margins. The revised criteria establishes a profitability threshold of less than or equal to 3% averaged consecutively over two or more of the last five cost reporting periods, as reported to the Centers for Medicare & Medicaid Services (CMS) in Cost Report filings. According to data released by HHS, five Pennsylvania hospitals will receive $89,558,187 through this subsequent safety-net distribution. Twenty-three Pennsylvania safety-net hospitals had received $311,746,422 in the original June distribution.

Rural and Small City Provider Distribution—HHS had previously provided $10 billion to rural health care providers. HHS is expanding the distribution to include certain special rural Medicare designation hospitals in urban areas as well as providers in smaller non-rural communities that may serve rural populations and operate with smaller profit margins and limited resources than larger hospitals. This distribution will provide $1,056,691,044 to 479 hospitals. Payments will range from $100,000 to $4,500,000 for rural designated providers and $100,000 to $2,000,000 for the other providers. According to data released by HHS, 21 Pennsylvania providers will receive $46,903,241. In the initial rural distribution during May, 156 Pennsylvania rural providers, including 48 hospitals, received a total of $231,148,801.

Dentists Eligible for Relief—Finally, HHS announced that the Enhanced Provider Relief Fund Payment Portal and an application process is available to dentists who have not yet been eligible for Provider Relief Fund dollars. Eligible dentists will receive a reimbursement of two percent of their annual reported patient revenue and will have until July 24, 2020, to apply for funding through the Enhanced Provider Relief Fund Payment Portal.

All providers receiving Provider Relief Fund payments must comply with the reporting requirements described in the Terms and Conditions and specified in future directions issued by the Secretary. Hospitals should continue to monitor updates posted online.

Why this matters: Even before the pandemic, hospitals in rural areas and hospitals serving high numbers of Medicaid and uninsured patients operated under serious financial pressure - these funds will help them continue to stay open and provide care to all who need it. This additional funding from HHS will help these hospitals carry out their mission of providing care close to home for their patients.

Hospital Groups Urge HHS to Delay Price Transparency Rule

The American Hospital Association, Association of American Medical Colleges, Children's Hospital Association, and Federation of American Hospitals, which brought a lawsuit challenging the Centers for Medicare & Medicaid Services’ hospital price transparency rule, last week urged the Department of Health and Human Services to delay the effective date of the rule until the matter is settled by the courts.
In a related move, a group of 34 state hospital associations also urged CMS to delay the effective date of the agency’s hospital price transparency rule until the issue is settled in the courts.

Background:
- Under the final rule issued during November 2019, hospitals are required to disclose the standard charges, including payor-specific negotiated rates, for all services beginning January 1, 2021.
- A federal judge recently dismissed the legal challenge to the final rule, which mandated that hospitals disclose their standard charges, including payor-specific negotiated rates with commercial health insurers, for all services beginning January 1, 2021. The AHA has appealed the decision and will seek to have it considered on an expedited basis.

Hospital industry perspective: “We anticipate the challenges associated with COVID-19 will continue for the foreseeable future, and perhaps until we develop and deploy a vaccine or reliable treatment,” the organizations wrote. “Resources of hospitals and health systems at this critical time must be devoted to patient care. While we disagree with the agency on the value of public disclosure of negotiated rate information (as opposed to estimated out-of-pocket costs), we hope that you will agree that advancing this policy is not essential at this moment.”

Hospital Financial Losses from COVID-19 Expected to Top $323 Billion in 2020
The American Hospital Association (AHA) recently issued a new report detailing the expected hospital losses from July 2020 to December 2020 as a result of COVID-19. This report complements an earlier AHA report, which estimated hospital losses from March 2020 to June 2020. In total, these reports indicate a catastrophic financial impact of more than $323 billion in 2020.

The losses attributed to hospitals are due in large part from mandated reductions in volumes at the onset of the pandemic to ensure hospitals were not overextended with COVID-19 patients. While many states are easing restrictions, many policies remain in place for hospitals such as stipulating bed capacity rates, requiring PPE reserves, and screening new patients and hospital staff.

View the report and infographic on AHA’s website.

Federal COVID-19 Policy Guidance and Other Developments
CMS Releases FAQs for state Medicaid and CHIP agencies: CMS posted additional FAQs to aid state Medicaid and Children’s Health Insurance Program agencies in their response to the COVID-19 pandemic. They also posted a standalone document containing only the new questions.

Senate Hearing Focuses on Vaccine Cost: The Senate held a hearing on “Operation Warp Speed: Focusing on Research, Manufacturing, and Distributing a Safe and Effective Coronavirus Vaccine”. Senators expressed concern over the affordability of the future coronavirus vaccine. Witnesses discussed the ability of the federal government to negotiate prices of the vaccine, particularly if the pharmaceutical company had received government funding.

Surgeon General Releases PSA: The U.S. Surgeon General and HHS released a public service announcement with steps for Americans to follow to help prevent the spread of COVID-19. These steps include:
• Follow federal, state and local guidelines;
• Take extra precautions if you are at higher risk for severe illness;
• Wash your hands frequently and thoroughly; and
• Stay six feet away from others when you can, and wear a face covering in public when you cannot social distance.

NGA Pushes for Emergency Renewal: The National Governors Association urged the Trump administration to renew the Public Health Emergency for COVID-19, currently set to expire July 25.

State Testing Plans Available: HHS made May and June COVID-19 Testing Plans from all states, territories, and localities publicly available on HHS.gov.

AHA Comments on Proposals to Prepare for Next Pandemic: The American Hospital Association outlined a number of actions Congress could take to help the nation prepare for the next pandemic, noting that the current pandemic also remains a challenge. The AHA provided the input on the ideas set forth in “Preparing for the Next Pandemic,” a white paper authored by Senator Lamar Alexander (R-TN). The AHA urged Congress to view preparedness from an all-hazard perspective so that we can best be prepared to respond to the next emergency, whether it is man-made, a weather emergency or an emerging novel virus.

Why this matters: America’s hospitals and health systems play a critical role in all types of disasters and public health emergencies. Often, as has been the case with COVID-19, they serve as the front line of response and collaborating with federal, state, and local emergency response teams, including carrying out a number of public health functions from testing to public education. Hospitals believe that there is much to learn from the COVID-19 pandemic and that there are significant opportunities to strengthen our nation’s preparedness and response capabilities and capacities.

Gilead Begins Clinical Study of Inhaled Remdesivir for COVID-19 Treatment: Gilead Sciences said it is starting phase one clinical study of inhaled remdesivir for potential outpatient treatment of COVID-19. In a statement, Gilead said the inhaled version could better target respiratory infections and limit systemic exposure to remdesivir and be accessible to non-hospitalized patients. In the placebo-controlled trial, Gilead said it will enroll approximately 60 healthy U.S. adults to evaluate the drug’s safety, tolerability, and pharmacokinetics.

Mount Sinai Joins Effort to Develop COVID-19 Hyperimmune Globulin Product Candidate: The Mount Sinai Health System will partner with Emergent BioSolutions and ImmunoTek Bio Centers on the development and evaluation of a COVID-19 hyperimmune globulin product, it was announced. The COVID-HIG is prepared using convalescent plasma from COVID-19 patients to potentially prevent and treat the disease in the absence of a vaccine. The collaboration, which leverages $34.6 million in funding from the Department of Defense, includes a post-exposure prophylaxis study on health care providers at high risk of COVID-19 infection and other high-risk populations.

CDC Begins Preparations for New Swine Flu Viruses: Earlier this month, The Centers for Disease Control and Prevention said it is taking steps to prepare for the possible spread of H1N1 swine influenza viruses. The group of viruses, labeled “G4” Eurasian avian-like H1N1 viruses, are believed to be highly adaptable for human infection.

The CDC said it is taking a number of actions to monitor and prepare against this emerging public health threat, including:
Coordinating with public health partners in China, including requesting a virus sample;
Assessing the risk of the virus causing a pandemic using CDC’s Influenza Risk Assessment Tool;
Evaluating whether an existing candidate vaccine virus against a closely related flu virus (called “G5”) would protect against this virus;
If needed, creating a new candidate vaccine virus specific to G4 viruses; and
Studying whether existing flu antiviral drugs offer protection against this group of viruses.

CDC Study Shows Rise in Essential Workers’ Health-related Absenteeism: Certain groups of workers showed significantly more absenteeism in March and April 2020, suggesting a link to COVID-19 exposure, according to a new study released by the Centers for Disease Control and Prevention. The report’s authors noted the findings are consistent with other public health surveillance and field investigations that suggest certain workers are at increased risk of COVID-19.

Point-of-care Antigen Test Earns FDA Emergency Use Authorization: The Food and Drug Administration authorized the emergency use of the BD (Becton Dickinson) Veritor System for Rapid Detection of SARS-CoV-2. The test is the second antigen diagnostic to earn an emergency use authorization from FDA and can be used in patient care settings approved for CLIA high or moderate complexity or waived testing. However, the test’s emergency use is limited to authorized laboratories using the BD Veritor Plus Analyzer Instrument.

Lysol Surface Disinfectants Gains First EPA Approvals as SARS-CoV-2 Killers: The Environmental Protection Agency approved two Lysol products following testing indicating that both safely and effectively kill the virus - SARS-CoV-2, which causes COVID-19 - on surfaces.

AHA, AAMC, and CHA Request Extension for Community Health Needs Assessments: The American Hospital Association, Association of American Medical Colleges, and Catholic Health Association of the United States requested the Department of Treasury and the Internal Revenue Service extend the deadlines for tax-exempt hospitals and health systems to prepare community health needs assessments that occur during the COVID-19 public health emergency.

They called on the IRS to “immediately announce an extension for any CHNA required to be conducted after April 1, 2020 until April 1, 2021 or a date that is six months after the expiration of the public health emergency declared by the Secretary of Health and Human Services,” whichever is longer.

HHS and DOD Collaborate to Produce COVID-19 Vaccines and Therapeutics: The Department of Health and Human Services and Department of Defense announced a $1.6 billion agreement to demonstrate commercial-scale manufacturing of Novavax, Inc.’s investigational COVID-19 vaccine. By funding this manufacturing effort, the federal government will own the 100 million vaccine doses produced through the demonstration. HHS and DOD also announced a similar agreement with Regeneron Inc. to demonstrate manufacturing of an investigational COVID-19 antiviral treatment. Under the agreement, the company said the U.S. could own between 70,000 and 300,000 doses of the therapeutic.

FDA Issues EUA for Test Differentiating Flu From COVID-19: The Food and Drug Administration authorized the emergency use of a third diagnostic test that detects and differentiates flu and COVID-19 viruses from one another. The test from the Centers for Disease Control and Prevention, along with previously authorized tests from BioFire Diagnostics LLC and QIAGEN GmbH, require only a single sample from patients who exhibit respiratory disease symptoms. FDA said these tests will use fewer supplies and provide faster and comprehensive results.
FDA Warns of ‘Life-threatening’ Methanol-based Hand Sanitizers, Authorizes New COVID-19 Test Kits: The Food and Drug Administration warned of methanol’s toxic and “not acceptable” suitability for use as an active ingredient in hand sanitizer. Methanol is a wood alcohol more commonly used for the creation of fuel or antifreeze. FDA said it has seen an increase in methanol’s use in hand sanitizers, resulting in adverse events among adults and children that include blindness, hospitalizations and death.

The FDA also authorized the emergency use of a trio of COVID-19 test kits:
- The TNS Co., Ltd (Bio TNS) COVID-19 RT-PCR Peptide Nucleic Acid for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens;
- The Kroger Health COVID-19 Test Home Collection Kit, which can be used by individuals to self-collect nasal swab specimens at home while video-observed by a health care provider; and
- Psomagen, Inc.’s Psoma COVID-19 RT Test, which is authorized for qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory swab specimens and bronchoalveolar lavage specimens.

SBA and Treasury Release Paycheck Protection Program Loan Data: The Small Business Administration and Treasury Department released detailed data regarding the loans made under the Paycheck Protection Program. Congress last week passed legislation extending the PPP loan application period through August 8. Organizations with fewer than 500 total employees, including hospitals, may apply to the program for loans of up to $10 million and have the loan amount forgiven if at least 60% of the loan goes to payroll expenses, among other requirements. The CARES Act created the forgivable loans to help eligible small businesses keep workers on the payroll during the pandemic. Congress then extended the loan period through December 31, and the timeframe for repayment if required, among other flexibilities.

COVID-19 Blanket Exceptions for Medicare Quality Reporting Programs End: The blanket data reporting exceptions and extensions implemented in March across Medicare quality reporting and value-based payment programs for hospitals expired July 1.

Specifically, the Centers for Medicare & Medicaid Services made it optional to submit data from the fourth quarter of 2019 (October through December) and the first two quarters of 2020 (January through March, and April through June); and will not use claims data from January 1 through June 30, 2020 to calculate performance in its quality reporting and value-based purchasing programs. CMS expects hospitals to collect and report data for the third and fourth quarters of 2020 in accordance with regular program requirements.CMS intends to address this issue further in a future rule.

While CMS’s blanket reporting exception has ended, hospitals unable to meet third and/or fourth quarter 2020 data collection and reporting requirements under the hospital quality reporting and value-based purchasing programs due to COVID-19 or another event beyond their control may use the programs’ existing policies to request an exception within 90 calendar days of the extraordinary circumstance.

FDA Issues Vaccine Development Guidance, Authorizes New Molecular-based COVID-19 Test: The Food and Drug Administration issued guidance for the development of a SARS-CoV-2 vaccine, outlining key considerations to satisfy requirements for chemistry, manufacturing and control, nonclinical and clinical data. The FDA also authorized the emergency use of the molecular-based LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel. The agency concluded that the qualitative test’s known and potential benefits outweigh the risks during the COVID-19 public health emergency.
HHS Reestablishes Ready Reserve Corps and Extends Public-private Partnership for COVID-19 Testing: The Department of Health and Human Services announced the reestablishment of the Ready Reserve Corps, a uniformed service that provides trained and ready personnel available on short notice to fill critical public health needs. The organization’s reestablishment as a part of the U.S. Public Health Service was authorized in March through the CARES Act.

HHS is also extending its partnership with national pharmacy and grocery retail chains CVS, Rite-Aid, Walgreens, Quest (through services at Walmart), and eTrueNorth (through services at Kroger, Health Mart, and Walmart) to expand convenient access to COVID-19 testing, the agency said.

FDA Issues EUAs for COVID-19 Tests, Resuscitator and Ventilator: The Food and Drug Administration authorized the emergency use of two COVID-19 molecular diagnostic tests. The tests from Inform Diagnostics Inc. and Diagnostic Solutions Laboratory LLC detect in respiratory specimens nucleic acid from SARS-CoV-2, the virus that causes COVID-19. The FDA also recently added an emergency resuscitator and a ventilator to its ventilator EAU list.

Layered Cotton Face Coverings May Best Slow COVID-19 in Public: Three of the five most effective cloth face coverings tested by the National Institute of Standards and Technology were 100% cotton and had a visible raised fiber or nap, such as found on flannels, the agency announced. The researchers tested how well 32 natural and synthetic fabrics filtered particles similar in size to the virus that causes COVID-19; none of them came close to the efficiency of N95 masks. The CDC recommends people wear cloth face coverings to help protect others in public settings where social distancing is difficult.

CDC Releases Results from Geographic Serology Survey: SARS-CoV-2 infections may be 10 times higher than reported cases, according to new data from a CDC partnership with commercial laboratories to test de-identified clinical blood specimens for antibodies in Connecticut, South Florida, the New York City area, Missouri, Utah, and western Washington state. CDC is working with state and local health departments to publish additional results from California, Louisiana, Minnesota, and Pennsylvania.

U.S. Supreme Court Upholds Revised ACA Contraceptive Coverage Exemptions
The U.S. Supreme Court issued a decision in Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania and two additional consolidated cases upholding recent Trump Administration interim final rules (“IFRs”) exempting certain entities from providing contraceptive coverage on certain religious or moral grounds.

The Supreme Court rejected certain plaintiffs’ claims that the agencies lacked authority to issue the IFRs and that the IFRs were procedurally defective under the Administrative Procedure Act. The Court ordered the lifting of a nationwide preliminary injunction issued by the Third Circuit and remanded the cases back to the lower courts for any further proceedings necessary to resolve any remaining claims plaintiffs may have raised.

Why this matters: The opinion, written by Justice Thomas, upholds two recent Trump Administration rules that expanded the existing exemption from the ACA’s contraceptive mandate. The rules finalized in 2017:
- Broaden the scope of entities eligible for an exemption based on sincerely held religious beliefs;
- Allow certain non-governmental employers, institutions of higher education, and health insurance issuers to claim an exemption from the mandate based on sincerely held moral beliefs;
- Allow exemption based on religious or moral objection to coverage of all or a subset of contraceptive services;
• Permit individuals to object to coverage of some or all contraceptive services based on religious or moral objections; and
• Make the existing accommodation process optional for exempt employers.

Administration Proposes Additional Flexibilities for Grandfathered Plans
A new proposed rule was issued by the tri-Departments (HHS, Labor, and Treasury) that specifically updates a 2015 final rule to permit grandfathered group health plans and group health insurance coverage to maintain their status of being exempt from certain ACA market reforms despite making increases to plan cost-sharing.

Specifically, the rule makes two main changes:
• Allows a high-deductible health plan to increase cost-sharing requirements, including deductibles, to the extent necessary to maintain status as an Health Savings Account-qualified high-deductible health plan; and
• For all grandfathered plans, provides an alternative method of implementing permitted increases in patient cost-sharing to more accurately reflect market changes in the cost of health coverage.

The primary aim of the rule is allowing grandfathered plans more flexibility to maintain their status to facilitate continuous coverage offerings to employees. The Departments estimate in the rule that 13% of all workers covered through employment are enrolled in grandfathered plans, including 5.6 million participants and beneficiaries covered by plans sponsored by state or local governments.

Comments to the proposed rule are due August 14, 2020.

CMS Proposes Medicare Payment Changes for Dialysis in the Home Setting
The Centers for Medicare & Medicaid Services (CMS) released proposed changes for calendar year 2021 to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) under the Original Medicare program (fact sheet). One proposal of note is an additional payment to ESRD facilities for certain costs of qualifying home dialysis machines.

Why this matters: CMS indicates the proposal is designed to respond to a number of developments, including the 2019 Executive Order on transforming kidney care focused on efforts to encourage home dialysis; various HHS home dialysis initiatives; and the need to provide ESRD patients with alternatives to in-center dialysis during the current COVID-19 pandemic and other public health emergencies.

Comments on the proposals are due September 4, 2020.

June COVID-19 Testing Plans from all states, territories, and localities publicly available on HHS.gov.

State Issues

Delaware
Legislative

State of Emergency Telehealth Waivers Extended to July 1, 2021
On the final day of session the Delaware General Assembly passed House Substitute 1 for House Bill 348 w/ House Amendment 1. This Act, which becomes effective upon signature of the Governor, continues certain provisions in the Declaration of a State of Emergency for the State of Delaware dated March 12, 2020 as a result of the COVID-19 pandemic as modified related to telemedicine through July 1, 2021.

- The Second Modification of the State of Emergency suspended all requirements that patients present in person before telemedicine services may be provided and the requirement that a patient must be in Delaware at the time the telemedicine services are provided; this Act continues the suspension of those requirements, but specifies that the requirement that a patient present in-person prior to the delivery of telemedicine services is excused under circumstances which make in-person presentation impractical.
- The Tenth Modification of the State of Emergency suspended any requirement in regulation that required both audio and visual technology; this Act prohibits any regulation pertaining to telemedicine requiring visual communication so as to permit telemedicine services via non-smart phones or land line connections.
- This Act also specifies that prescribing controlled substances including opioids prescribed via telemedicine is subject to the same standards of practice and includes a paragraph under existing law pertaining to authorization for APRNs to prescribe controlled substances and adds the authority to prescribe opioids by electronic means.

Why This Matters: The waiver extension of telehealth regulations assures the continuance of access to important health care services amid the COVID-19 pandemic.

State Issues

Delaware
Regulatory

Insurer Requirements Issued for Policy Cancellations, Non-renewals and Repayment Plans
The Delaware Department of Insurance has issued an update to Bulletin No. 117 in light of the 23rd modification to the State of Emergency declaration and the lifting of the moratorium on cancellations and nonrenewal of policies. The modification contains several requirements for insurers regarding implementing the end of the moratorium on cancellations and non-renewals and establishing premium repayment plans.

State Issues

Pennsylvania
Legislative

Governor Wolf Signs Health Care Bills
Governor Tom Wolf signed several bills into law just before the Independence Day holiday:

Breast Prosthetic Device Definition and Coverage – Act 44 of 2020
- **House Bill 1457** (Act 44 of 2020) amends the Insurance Company Law addressing health insurance coverage for mastectomy and breast cancer reconstruction to clarify that the term “prosthetic devices” also includes “custom artificial devices.” Existing law does not include any references to custom prosthetic devices. **Act 44 of 2020 was signed on July 1 and is effective in 60 days/August 30, 2020.**

**Breast MRI / Ultrasound Bill Mandate – Act 52 of 2020**
- **Senate Bill 595** (Act 52 of 2020) expands breast cancer screening by requiring full cost coverage of annual and physician-recommended mammographic examinations, including Magnetic Resonance Imaging (MRI) or ultrasound screening, if the treating physician believes the woman is at an increased risk for breast cancer. **Act 52 of 2020 was signed on July 1 and is effective in 60 days/August 30, 2020.**

**Health Care Worker Assault Penalties – Act 51 of 2020**
- **Senate Bill 351** (Act 51 of 2020) amends Section 2702 (Aggravated Assault) of Title 18 (Crimes and Offenses) to add “health care practitioner or technician” to a protected class in the event of an assault, and increases the penalty for an assault on a health care worker from a misdemeanor of the second to a felony of the second degree. **Act 51 of 2020 was signed on July 1 and is effective in 60 days/August 30, 2020.**

**Photo Identification Badge Requirements – Act 54 of 2020**
- **Senate Bill 842** (Act 54 of 2020), a workplace safety initiative, amends the Health Care Facilities Act to eliminate a state requirement for photo identification badges in health care facilities to include the employee’s last name. Last names can be omitted or concealed. **Act 54 of 2020 was signed on July 1 and is effective in 60 days/August 30, 2020.**

**Senate Advances NAIC Model, Medicaid PBM Bills**
Just prior to the Fourth of July recess, the Senate considered several bills of interest to Highmark:
- **Senate Bill 1195** amends the Insurance Company Law to enact National Association of Insurance Commissioners (NAIC) model legislation addressing credit for reinsurance. Highmark staff was instrumental in amending the bill to expand the offset provisions to permit Highmark nontaxable (state premium tax) entities to recoup any guaranty association assessments. Senate Bill 1195 was approved 50-0 and referred to the House Insurance Committee for further consideration.
- **House Bill 941** permits the Department of Human Services (DHS) to conduct an audit or review a pharmacy, pharmacy benefit manager (PBM), pharmacy services administration organization or other entity that manages, processes, influences the payment for or dispenses pharmacy services to Medicaid Managed Care Organization (MCO) clients. The bill also mandates the use of the National Average Drug Acquisition Cost (NADAC) and a dispensing fee to calculate reimbursement for pharmacies. The legislation is on the Senate voting calendar.
- **House Bill 943** prohibits Pharmacy Benefits Managers (PBMs) from including “gag clauses” in pharmacy network contracts, in order to prohibit pharmacies from sharing cost data regarding prescription drugs to an insured. The measure, approved 50-0, was also approved by the House and now awaits signing by Gov. Wolf.
Testing Proposal Clears House State Government Committee
The House State Government Committee has approved legislation that ensures the availability of COVID-19 testing to employees and residents at licensed nursing facilities, assisted living residences and personal care homes. House Bill 2543 was amended to include language requiring a nursing resident or staff member to report testing to their insurance carrier, and if not covered, the Department of Health would pay for the testing through the Federal CARES funds. The sponsor of the amendment, Rep. Russ Diamond (R-Lebanon), clarified that the bill does not mandate testing for staff and residents but ensures access to its availability.

State Issues

Pennsylvania
Regulatory

DHS Solicits Contractor Interest in a Statewide Resource and Referral Tool
On July 8, 2020, the Pennsylvania Department of Human Services (DHS) publicly released a Request for Expressions of Interest (RFEI) to procure a contractor to provide a person-centered statewide resource and referral tool. The tool will serve as a care coordination system for providers such as health care and social services organizations and will report on the outcomes of the referrals, while allowing Pennsylvanians to find and access the services they need to improve health outcomes.

How it works: The tool, when implemented, will allow providers to assess a person’s health or social service needs during a physician’s office or emergency department visit, or when receiving case management services, among others.

Individuals, service providers, government agencies, caregivers, educational institutions, faith-based groups, and advocates also will be able to use this tool to help navigate the system of resources and work together to reduce duplication of services and the time it takes for individuals to receive the much-needed services.

Why this matters: Addressing social determinants of health—including employment, childcare, transportation, food security, access to health care, and housing stability—helps individuals achieve better long-term health outcomes and maximizes the impact of health care dollars. This project has been in development for some time as DHS has long advocated for a centralized, easy-to-navigate system that would help individuals and families in need of assistance. The tool should close the gaps that currently make service continuity and follow-up on referrals difficult. Responses to the RFEI are due August 6, 2020.

Department of Health Issues FAQs on Travel Recommendations
The Department of Health has issued an FAQ document to provide additional detail surrounding the Wolf Administration’s recommendation for domestic travelers returning from certain states with high numbers of COVID-19 cases to quarantine for 14 days upon return to Pennsylvania. The FAQ reiterates that quarantine related to travel is a recommendation, not a requirement. It also provides clarity that the recommendation applies to all people in Pennsylvania, including health care workers.
Health care workers should follow their healthcare facility’s policy and procedure, and healthcare facilities should inform their policy and procedure through the Centers for Disease Control and Prevention (CDC) guidance and PA-HAN-513 or its successor. PA-HAN-513 refers to PA-HAN-501 to govern health care personnel with health care-related exposures.

Why this matters: Hospitals need to incorporate the administration’s quarantine recommendations into existing policies and procedures for health care workers consistent with organization needs and preferences.

A list of states to which the quarantine recommendation applies is on the PA DOH Travelers Information website.

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State Issues

West Virginia

Regulatory

Governor Justice Appoints New Public Health Officer

Governor Jim Justice has appointed Dr. Ayne Amjad, a Beckley physician, as West Virginia’s new Public Health Officer. Since 2010, Amjad has been a private practice physician specializing in internal medicine and preventive health care serving residents in Beckley, Oak Hill and Princeton. She also is the assistant program director of Encompass Health in Princeton and the medical director of PCH Home Care in Beckley.

Amjad replaces Dr. Cathy Slemp, who resigned June 24 following complaints made by Governor Justice regarding the accuracy of coronavirus data.

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Industry Trends

Policy / Market Trends

HHS Releases Second Report on Social Risk Factors and Impact on Medicare Quality Programs

The Department of Health and Human Services (HHS) released the Report to Congress: Social Risk Factors and Performance in Medicare’s Value-Based Purchasing Programs, the second of two reports mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The main findings of the second report conclude that:

- Social risk information is not routinely or systematically collected across the health care system;
- Dual-enrollment status and functional status remain strong predictors of poor outcomes on some quality measures; and
- Many organizations are working to improve equity by addressing social risk factors, and more evaluation is needed to assess which interventions are effective, replicable, and scalable.
The report also includes detailed recommendations to move Medicare’s Value Based Purchasing (VBP) programs towards incentivizing providers and plans to improve health outcomes by rewarding and supporting better outcomes for beneficiaries with social risk factors. These include:

- Measure and report quality by social risk;
- Reward and support better outcomes for all beneficiaries, including those with social risk factors; and
- Hold providers to the same high, fair quality standards for all beneficiaries.

The report also addresses categorical adjustments for social risk factors in Medicare VBP programs, including the categorical adjustment index (CAI) used in MA Star Ratings.

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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