

Federal Issues

Legislative

Congress Examines Rx Bills, Black Maternal Health

Last week, committees in the U.S. House held hearings to examine competing Democratic and Republican proposals that aim to lower the cost of prescription drugs as well as efforts to reduce disparities in maternal health.

- The House Energy and Commerce Subcommittee on Health met on Tuesday for a [hearing](#) titled “Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs.” The hearing focused on eight prescription drug reform proposals, including House Democrats’ Elijah E. Cummings Lower Drug Costs Now Act ([H.R. 3](#)) and House Republicans’ Lower Costs, More Cures Act of 2021 ([H.R. 19](#)). During the hearing, lawmakers from both parties debated their proposals and heard testimony from patient advocates, academics and the provider community.
- **Outlook:** H.R. 3, a bill which allows Medicare to negotiate drug prices, among other policies, has little chance to become law through regular order because of the 50-50 split within the

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Senate. Democrats are also focusing their efforts on President Biden's American Jobs Plan and American Families Plan, neither of which include the prescription drug legislation; however, a number of senior Democratic members are advocating for its inclusion. House Speaker Nancy Pelosi (D-CA) is looking to pass an infrastructure package within the coming months, although its pathway is still unknown. If Democrats can hold their party together, it is likely that they will utilize the reconciliation process again to bypass Senate Republicans.

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- In addition, on Wednesday, the House Education and Labor Subcommittee on Health, Employment, Labor and Pensions held a [hearing](#) titled "Lower Drug Costs Now: Expanding Access to Affordable Health Care." The hearing similarly focused on the Democrats' and Republicans' preferred bills, and included testimony from multiple health policy experts.
- On Thursday, the House Oversight and Reform Committee held a [hearing](#) titled "Birthing While Black: Examining America's Black Maternal Health Crisis," which focused on the causes of the Black maternal health crisis, as well as potential federal solutions to this crisis. Many of the witnesses provided firsthand accounts of their experiences with maternal health care and identified issues for policymakers to address. Both [AHIP](#) and [BCBSA](#) submitted statements for the record outlining health plans' efforts to reduce disparities.

Federal Issues

Regulatory

Summary of 2022 Payment Notice Final Rule

The Department of Health and Human Services published in the [Federal Register](#) the Notice of Benefit and Payment Parameters to issuers offering coverage on the Federal Exchanges in 2022. This is the second final rule published for the 2022 plan year—earlier this year, the Trump Administration finalized a [partial](#) Payment Notice final rule adopting a narrow set of provisions for plan year 2022.

Why this matters

- In general, this final rule reflects modest changes to some of the Trump-era policies but previews more significant changes to come in the future (for example, rolling back Section 1332 state innovation waiver regulations, revisiting network adequacy standards).

- For example, the Biden administration did not reverse prior policies reducing the user fee on plan premiums which is used to help finance the operations of the Federal Exchange, but has signaled that the policy may be revisited.
- The administration also moved forward with a Trump-era policy to allow on- and off-Exchange individual health insurance coverage options to be displayed side-by-side on the websites of web-brokers and direct enrollment issuers when assisting individuals who have communicated receipt of an offer of an individual coverage health reimbursement arrangement, a special account-based plan established by the Trump administration to help employers finance health coverage without offering a group health plan.

The Biden administration did not finalize some proposals, however. CMS is not requiring all Exchanges to verify eligibility for a special enrollment period for at least 75% of new enrollments due to the administrative burdens this could pose to individuals and exchanges. In a win for consumer advocates and in the interest of lowering out-of-pocket costs for enrollees, CMS is reverting back to the premium adjustment percentage index used for benefit years 2015 to 2019. This will result in a maximum out-of-pocket cost maximum that is \$400 less than the proposal.

More info: CMS released additional guidance related to plan year 2022 for qualified health plan issuers in the Exchanges, including the Final 2022 [Letter](#) to Issuers in the Federally-facilitated Exchanges and the Final 2022 Actuarial Value (AV) [Calculator](#) and accompanying methodology. CMS also released updated [Frequently Asked Questions](#) clarifying which telehealth services are valid for the HHS-operated risk adjustment for the 2020 benefit year.

CMS to Increase Payment Rate for Administering Monoclonal Antibodies

On May 6, the Centers for Medicare & Medicaid Services (CMS) announced that it [will increase the Medicare payment rate for administering monoclonal antibodies](#) to treat beneficiaries with COVID-19, continuing coverage under the Part B COVID-19 vaccine benefit.

Why this matters: CMS increased the national average payment rate from \$310 to \$450 for most health care settings. In support of providers' efforts to prevent the spread of COVID-19, CMS will also establish a higher national payment of \$750 when monoclonal antibodies are administered in the beneficiary's home, including the beneficiary's permanent residence or temporary lodging (e.g., hotel/motel, cruise ship, hostel, or homeless shelter). Beneficiaries pay nothing out of pocket, regardless of where the service is furnished. These higher national average payment rates reflect additional information provided to CMS about the costs of provided these services in a safe and timely manner, such as clinical staff and personal protective equipment (PPE). This also means Medicare payments to providers and suppliers will be more aligned with their costs to administer these products.

Nearly 940,000 Enrolled in Healthcare.gov Plans During Special Enrollment Period

The U.S. Department of Health and Human Services (HHS) [announced](#) nearly 940,000 Americans have signed up for coverage through healthcare.gov from the beginning of the 2021 Marketplace Special Enrollment Period (SEP) through April 30.

The Centers for Medicare and Medicaid Services (CMS) 2021 Marketplace SEP [Report](#) showed 469,000 of those plan selections occurred during April, the first month during which enhanced subsidies under the

American Rescue Plan Act were available. This enrollment figure is 45 percent higher than the 322,000 who [obtained coverage](#) through the SEP in March and represents a substantial increase over the enrollment numbers recorded during the same time periods in 2020 and 2019, which were 391,000 and 266,000 respectively.

Since April 1, 1.9 million existing enrollees returned to healthcare.gov to take advantage of enhanced ARPA subsidies and reduced their monthly net premiums by an average of 40 percent, from \$100 to \$57. Out-of-pocket costs have also decreased– the median deductible for new SEP enrollees fell by 90 percent, from \$450 prior to April 1 to \$50 following April 1. Consumers in healthcare.gov states have until August 15 to enroll in coverage or update their application to access enhanced subsidies. These data do not include SEP enrollments in the fifteen states that run their own exchange websites.

Coronavirus Updates

- The Biden Administration announced a new vaccine distribution strategy allowing states to order COVID-19 vaccine supply not being used in other states. This new strategy aims to match vaccine supply to areas where there is higher demand and reflects the Administration’s efforts to reach vaccine hesitant or unmotivated Americans.
- The Department of Health and Human Services (HHS) [announced](#) the availability of nearly \$1 billion to strengthen COVID-19 response efforts and increase vaccinations in rural communities. Using funds provided by the American Rescue Plan, HHS will increase the number of vaccines sent to rural communities, expand testing and other COVID-19 prevention services, and work to increase vaccine confidence by empowering trusted local voices with additional funding for outreach efforts in underserved communities.
- The Department of Health and Human Services (HHS), through the Health Resources and Services Administration (HRSA), announced a new program covering costs of administering COVID-19 vaccines to patients enrolled in health plans that either do not cover vaccination fees or cover them with patient cost-sharing. The types of plans referenced under this Fund include grandfathered group health plans, excepted benefits, and short-term limited duration insurance. The [COVID-19 Coverage Assistance Fund \(CAF\)](#) will be compensating providers for eligible claims at national Medicare rates which increased in March. For more information, please see this [fact sheet](#) and [FAQs](#).
- The U.S. Treasury began giving state and local governments access to \$350 billion in emergency funding from the American Rescue Plan, the department announced Monday.
- The Centers for Medicare & Medicaid Services (CMS) released an update to the Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and Cost Sharing under Medicaid, CHIP, and BHP vaccine [toolkit](#). This revised toolkit discusses a variety of updates such as:
 - The expansion of the mandatory benefit for vaccine and vaccine administration coverage to all nearly Medicaid beneficiaries as required by the American Rescue Plan Act (ARP).

- The enhanced 100% federal match for COVID-19 vaccines and their administration as provided for in the ARP.
 - The authorization of the Janssen (Johnson & Johnson) vaccine.
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GAO Report Highlights Behavioral Health Needs During Pandemic

A report published by the U.S. Government Accountability Office (GAO) attempts to answer the question of how, if at all, the need and availability of mental health and substance use disorders have changed during the COVID-19 pandemic. Echoing CDC reporting, the GAO concludes that symptoms of anxiety and depression increased dramatically (38%) over a 10-month period, and that emergency department visits for drug overdoses and suicide attempts were also higher during a six-month period in 2020 as compared to the same period in 2019. The GAO also cited a survey by a provider organization, the National Council of Behavioral Health, which found demand for services increasing among two-thirds of members surveyed. This demand came at the same time that offices or programs closed or laid off staff, potentially exacerbating the access issues.

While the GAO report did not offer comprehensive recommendations, the findings may be helpful for policymakers in the continued COVID-19 response, as well as developing contingency planning for future pandemics.

State Issues

Delaware
Regulatory

Major Changes to Delaware's COVID-19 Restrictions to Take Effect May 21, 2021

Gov. John Carney and the Delaware Division of Public Health [announced several major changes to Delaware's COVID-19 restrictions](#).

Effective Friday, May 21:

All capacity restrictions inside restaurants, retail, other business establishments and houses of worship will be lifted. Facilities will be able to use as much capacity as social distancing requirements will allow. Masks will still be required indoors to prevent spread of COVID-19.

Read the full press release from the governor [here](#).

State Issues

New York
Legislative

Legislation Advances Prohibiting Mid-Year Formulary Changes by Health Plans

With five weeks left in the legislative session, a number of health care bills are moving through the legislature and are on the agendas of various legislative committees this week.

Mid-year formulary prohibition: Would prohibit health plans from making changes to their formularies except during the renewal and enrollment period leading up to the start of an employer's or individual's policy year. The bill has passed the Senate and is in the Assembly Ways and Means Committee.

Last week several business groups including the Buffalo-Niagara Partnership, Business Council of Westchester, Capital Region Chamber, NFIB, the Rockland Business Association, and the NY State Association of Health Underwriters, issued a memo in opposition to the bill. The groups raised concerns that the bill excludes labor unions from the requirements, setting two different standards – one for labor unions and another for small employers – and also said the bill would leave fewer options for employers to control pharmaceutical costs leading to higher health insurance premiums.

Telehealth parity reimbursement: Would require telehealth visits be reimbursed at the same rate as in-person visits. The bill is in the Assembly Insurance and Senate Finance Committees.

MAT prior authorization prohibition: Prohibits prior authorization for medication assisted treatment for substance abuse disorders. Senate bill is in Health Committee; Assembly bill in Ways and Means Committee.

State Issues

Pennsylvania

Legislative

Health Committee Advances Immunization Freedom Act and Insurance Coverage for Long-Term Antibiotic Treatment for Lyme Disease

On Wednesday, May 5, the House Health Committee advanced the following bills:

[House Bill 958](#), (Zimmerman, R-Lancaster) Would prohibit a health care practitioner from providing care to a pediatric patient when a parent or legal guardian chooses to vaccinate the child on schedule that varies from CDC recommendations. Additionally, House Bill 958 would prohibit health insurers from providing financial incentives to a health care practitioner to provide vaccinations.

Why this matters: Prohibiting health insurers from financially incentivizing health care practitioners to follow vaccine clinical best practices and require coverage outside of the clinical guidelines for vaccines would disrupt many value based reimbursement arrangements.

[House Bill 1033](#), (Rapp, R-Warren) Would require health insurers to cover treatment plans for Lyme disease or related tick-borne illnesses as prescribed by a patient's health care practitioner, regardless if the treatment plan includes short-term or long-term antibiotic treatment.

Why this matters: Long-term antibiotic therapy does not align with the current clinical practices for the treatment of Lyme Disease and in some cases poses significant harm to patients.

Legislative Initiative Proposed to Help Hospitals Recover from COVID Pandemic

Last week, the hospital industry and key legislators held a press conference to unveil the "Health Care Heroes and Public Health Preparedness (PA Heroes) Act," which was introduced in the state General Assembly.

Representing hospitals at the press conference was the President and CEO of the Hospital & Healthsystem Association of Pennsylvania, Andy Carter. Also participating were: State Senator Camera Bartolotta (R-Beaver, Greene, Washington), prime sponsor of [Senate Bill 642](#), State Representatives Greg Rothman (R-Cumberland) and Stephen Kinsey (D-Philadelphia), co-prime sponsors of [House Bill 1359](#).

Also participating:

- Lou Panza, president and CEO, Monongahela Valley Hospital, who outlined the ways that the PA Heroes Act could support public health infrastructure and projects to bolster the resilience of the health care workforce.
- Dr. Erika Saunders, chair, Department of Psychiatry and Behavioral Health, Penn State Health, who discussed the ways that the PA Heroes Act could address critical deficiencies in access to behavioral health services, including through telehealth.

Background: As part of the federal American Rescue Plan Act, Pennsylvania will receive \$7.293 billion dollars and other directed resources to help the state address the pandemic and its economic fallout. These dollars can be used to respond to or mitigate COVID-19 and its economic impact.

A significant portion of this amount will be made available to promote key commonwealth priorities related to COVID-19—such as restoring the health care workforce, strengthening the public health infrastructure, and addressing behavioral health capacity.

Grant Program Proposal Overview: To address the needs of the hospital workforce, communities, and the economy as a whole, the Health Care Heroes and Public Health Preparedness Act will:

- Allocate \$650 million in federal funding to the program
 - Create defined award criteria
 - Delegate responsibility for distributing grant funding to an appropriate administrative agency
 - Distribute funds based on demonstrated need until depleted
 - Ensure that funds could not be used to reimburse expenses or losses that have been fully reimbursed from other sources
 - Require grant recipients to submit applicable reports and maintain documentation subject to audit by the state Office of the Auditor General
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Regulatory

Pennsylvania Insurance Department Publishes Final Annual Attestation Required Under Acts 89 and 92

The Pennsylvania General Assembly of the Commonwealth enacted Acts 89 and 92 relating to mental health parity and access to addiction treatment and added to the Insurance Company Law of 1921 by requiring annual attestation of efforts to comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addition Equity Act of 2008 (MHPAEA) and Federal regulations regarding parity in mental health and substance use disorder benefits (MH/SUD Parity Federal regulations). In addition, Congress recently amended MHPAEA regarding compliance with nonquantitative treatment limitation requirements.

Accordingly, the Pennsylvania Insurance Department (Department) provides the following guidance to insurers seeking to demonstrate compliance with the annual attestation requirements established under Acts 89 and 92.

Acts 89 and 92 require insurers to annually file a statement with the Department attesting to either the insurer's efforts to comply with MHPAEA and the MH/SUD Parity Federal regulations, or the nonapplicability of MHPAEA, as to the form for each health insurance policy offered, issued or renewed by an insurer. Attestation filing requirements apply to forms for each insurance policy to be offered, issued or renewed in the Commonwealth after December 31, 2021.

For more information regarding the Attestation and filing requirements, the full Notice is available at: <https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol51/51-19/729.html>

Hospitals Respond to Gov. Wolf Executive Order Sustaining COVID-19 Regulatory Relief

On April 7, 2021, Governor Wolf issued an Executive Order No. 2021-03, that calls on agencies to recommend actions to reduce or eliminate regulatory impediments to economic, health and safety, and employment recovery. The Hospital & Healthsystem Association of Pennsylvania (HAP) responded to the executive order by sending letters with the hospital community's recommendations to the Pennsylvania Department of Human Services (DHS) and Pennsylvania Department of State (DOS).

HAP's recommendations to DHS and DOS include:

1. **Telehealth:** Encouraging the continuation of telehealth service without disruption of services. Telehealth services have become a vital means of service for vulnerable populations that are unable to attend medical visits due to lack of transportation or lack of willingness to attend in-person care. Additionally, telehealth services have provided another avenue for the treatment of behavioral health care needs, opening the door to more behavioral health practitioners
2. **Prior Authorization:** Requesting managed care plans waive all preauthorization reviews and pay clean claims from in-network hospital inpatient services and emergency services, and recommending managed care plans do not perform retrospective reviews for inpatient services and emergency service for in-network patients with a diagnosis related to the state health emergency
3. **Physician Assistants:** Recommending continuing the waivers that allowed physician assistants more flexibility in their scope of practice

4. **Certified Registered Nurse Practitioners (CRNP):** Supporting continuing to allow CRNPs to work without a written and signed collaborative agreement
5. **Certified Registered Nurse Anesthetists (CRNA):** Recommending the continuation of allowing CRNAs to administer anesthesia in cooperation with any physician instead of restricting administration of anesthesia only be done with a surgeon

Why this matters: Pennsylvania needs a coordinated transition to address the state's COVID-19 waivers and flexibilities after the pandemic ends. These enhanced flexibilities have played an important role to ensure safe care during the pandemic and will continue to benefit patients and providers into the future. Hospitals continue to advocate for [House Bill 1011](#), the Retaining Health Care Innovations Act, which includes the recommendations above and others that should be made permanent after the public health emergency subsides.

The Pennsylvania Senate is in session May 10-12. The Pennsylvania House returns to session on May 24.

The Delaware Legislature is in session May 11-13.

The New York Legislature is in session May 14 -15.

The West Virginia Legislature concluded session on April 10.

Congress

The U.S. House is in session May 11-14. The U.S. Senate is in session May 10-14.

Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: <http://legis.delaware.gov/>.

New York Legislation: <https://nyassembly.gov/leg/>

Pennsylvania Legislation: www.legis.state.pa.us.

West Virginia Legislation: <http://www.legis.state.wv.us/>

For copies of congressional bills, access the Thomas website – <http://thomas.loc.gov/>.

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