

Federal Issues

Legislative

House Passes Health Care Bills

The U.S. House passed a number of health care bills last week, including the [Protecting Moms Who Served Act](#). The legislation invests in Department of Veterans Affairs (VA) programs to implement maternity care coordination and requires the Government Accountability Office (GAO) to report on maternal mortality and severe maternal morbidity among pregnant and postpartum veterans. The legislation is part of the Black Maternal Health ["Mominibus"](#) package.

In addition, House lawmakers on Tuesday voted to advance [several other health-related bills](#), including several bills to address mental health policy and the COVID-19 pandemic. The measures now head to the Senate for consideration.

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Committees Hold Hearings on COVID-19, HHS Budget

Two committees examined health-related issues on Capitol Hill last week:

- The Senate Health, Education, Labor and Pensions (HELP) Committee held a [hearing](#) Tuesday on the federal government's response to the COVID-19 pandemic. The hearing featured some of the Biden Administration's top public health officials and largely focused on the federal government's ongoing strategy for mitigating the COVID-19 pandemic. **Notably, White House advisor David Kessler [indicated](#) during the hearing that the federal government has sufficient funds to be the sole purchaser of COVID-19 vaccines through 2022 for another round of booster shots, if necessary.**
- On Wednesday, lawmakers on the Energy and Commerce Subcommittee on Health held a [hearing](#) with HHS Secretary Xavier Becerra to discuss the Department's budget request for FY 2022. During the hearing, Democratic lawmakers defended the budget increase for HHS, citing the need to invest in public health preparedness and the Strategic National Stockpile, maternal health, Community Mental Health Services Block Grants, among other provisions. In contrast, Republican subcommittee members raised concerns about unspent COVID-19 relief funding, the Administration rescinding the extension of Texas' 1115 Medicaid waiver and pushed their drug pricing plan, H.R. 19, as a bipartisan alternative to the [House Democrats' H.R. 3](#), pointing out that H.R. 19 contains 36 bipartisan measures compiled from other proposed legislation. The path to being signed into law is still unknown for both these pieces of legislation, though Committee Chair Frank Pallone (D-NJ) expressed general support for some drug pricing reform. Importantly, the beginning of the budgetary process for fiscal year 2022 opens the opportunity for Democrats to utilize the reconciliation process which will likely be needed to pass the Biden administration's infrastructure package.

Federal Issues

Regulatory

HHS to Resume Enforcing ACA Nondiscrimination Standard Based on Sexual Orientation, Gender Identity

The Department of Health and Human Services' (HHS) Office of Civil Rights (OCR) [announced](#) it will interpret and enforce Section 1557 of the Affordable Care Act (ACA)'s nondiscrimination requirements to include sexual orientation and gender identity. This update was based on the June 2020 Supreme Court

decision in [Bostock v. Clayton County](#) and subsequent court decisions. The change in policy reflects the Biden administration's and the Justice Department's interpretation that the 2020 U.S. Supreme Court decision, *Bostock v. Clayton County, Georgia* that Title VII of the Civil Rights Act of 1964 applies to sexual orientation and gender identity also extends to Section 1557 of the ACA by virtue of the similarity of the statutes and reasoning. HHS further clarified this interpretation will guide OCR in processing complaints and conducting investigations but does not itself determine the outcome of any particular case or set of facts.

Why this matters:

- This declaration reverses Trump administration policies that defined “sex” to mean gender assigned at birth, thereby excluding transgender people from the law's umbrella of protection.
- Prior to the Biden administration announcement, HHS OCR and the Centers for Medicare and Medicaid Services (CMS) under the Trump administration [finalized a rule](#) in June 2020 to update an [earlier final rule](#) published in May 2016 under the Obama administration to codify nondiscrimination requirements and set forth new standards for implementing Section 1557.
- The change does not automatically change the status of new Section 1557 regulations which are still in development. The Biden administration is likely to revisit the 1557 rule, including language services and notice requirements, in the coming months.
- Recently, in the [Final 2022 Letter to Issuers](#) impacting plans on the Federal Exchange, CMS indicated it strongly encourages Qualified Health Plan (QHP) issuers to continue to meet tagline standards but will reissue rulemaking to reaffirm these standards.

Insurer viewpoint: Insurer groups supported the decision and federal law protections that prohibit discrimination based on gender identity, sexual orientation, or pregnancy status. “We applaud today’s announcement, which reinstates practices to ensure that everyone—including Americans who identify as members of the LGBTQIA community—has access to health care without any discrimination,” stated Matt Eyles, president and CEO of America’s Health Insurance Plans (AHIP).

CMS Clarifies New Interoperability Standards

The Centers for Medicare & Medicaid Services (CMS) [issued](#) a series of frequently asked questions addressing various aspects of implementation of new health data interoperability standards which apply to health plans and providers.

The guidance largely compiles subregulatory guidance in the CMS interoperability final rule and statements by CMS staff provided in webinars to stakeholder groups.

- Importantly, no additional relief was announced to delay the compliance deadline for the provisions, many of which have passed or are close on the horizon.
- CMS did provide more details to identify the vehicle CMS will use evaluate compliance, such as using an annual survey instrument for Medicare Advantage plans.

- CMS also clarified that a health plan's implementation costs for interoperability would be counted as quality improvement activities for purposes of the medical loss ratio calculation, which requires a certain percentage of premium dollars (80-85% typically) to be spent towards claims or quality activities.
 - Additional guidance addresses the requirement for hospitals to notify other providers about admissions, discharges and transfers as a Medicare condition of participation and the requirement for providers to update digital contact information through CMS's provider database, NPPES.
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Two More Trump Drug Policies Slated for Changes by Biden Administration

The Biden administration took additional concrete steps to review and revisit Trump-era drug policies, as evidenced by two proposed rules which are pending and may be published soon. First, the Office of Management and Budget [completed a review](#) of a new proposed rule which will make changes to the December 2020 final rule entitled, "Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Payments (VBP) for Drugs Covered in Medicaid."

This Trump administration policy attempted to encourage commercial value-based payment (VBP) arrangements for prescription drugs by creating flexibilities and periodic reporting of prescription drug best price points subject to VBP arrangements to allow Medicaid programs to opt in to these arrangements or continue to receive a traditional Medicaid drug rebate. The rule also attempted to limit the use of patient assistance programs by drug manufacturers to require the full amount of such payments to be passed on to the patient in order to exclude such payments from the Medicaid Best Price Rule, among other policies.

The [second proposed rule pending release](#) is expected to rescind the final rule requiring federal health care centers to provide certain insulin and epinephrine medications at or below the price the health center purchased them through the 340B drug discount program. The discounts would be available for individuals with incomes at 350% of the federal poverty level or below if they are uninsured or have high out-of-pocket costs.

Coronavirus Updates

- The Food and Drug Administration (FDA) [expanded](#) the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine to include individuals ages 12 to 15 years old. Last week, the company applied for full U.S. approval of its vaccine for people 16 to 85. Pfizer and BioNTech are studying the safety and efficacy of their vaccine in children from 6 months to 11 years old. The companies hope to have results for children ages 2 to 11 by September.
- The Treasury Department [announced](#) a \$350 billion state, local, territorial and tribal aid program established by the American Rescue Plan Act. Under the terms of the program, eligible governments can directly access funds to respond to acute pandemic-response needs, fill revenue shortfalls among state and local governments, and support the communities and populations hardest-hit by the crisis.

- A new Centers for Disease Control and Prevention (CDC) [report](#) analyzed demographic and social factors associated with COVID-19 vaccination among older adults. The report found that **counties with lower vaccination initiation rates had higher percentages of older adults with social vulnerabilities**, such as those lacking internet access or transportation options. The report concludes that state and local governments need to continue targeted outreach and prioritize efforts to ensure equitable access to COVID-19 vaccines. Understanding these challenges, AHIP and BCBSA [launched](#) the Vaccine Community pilot initiative in March to vaccinate 2+ million seniors in the most vulnerable communities. Last week AHIP, BCBSA and ACAP announced an expansion of the program to focus on Medicaid beneficiaries.
 - On May 11, CMS issued an interim final [rule](#) requiring long-term care (LTC) facilities and residential facilities serving clients with intellectual disabilities to educate residents, clients, and staff about the vaccine, as well as offer access to it. The rule also requires LTC facilities to report weekly COVID-19 vaccination status data for both residents and staff. The new vaccination reporting requirement will assist in monitoring uptake amongst residents and staff as well as in identifying facilities that maybe in need of additional resources and/or assistance to respond to the COVID-19 pandemic. The rule is effective on May 21 and CMS is accepting comments until July 12.
 - The Centers for Disease Control and Prevention (CDC) revised [guidelines](#) to clarify fully-vaccinated individuals can gather indoors and outdoors with other individuals without masks, even if some in their group are unvaccinated.
 - The Biden Administration [announced](#) it was investing \$7.4 billion in funds from the American Rescue Plan to help states and the federal government hire and recruit public health workers to conduct vaccinations, testing, contact tracing, and community outreach.
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HHS Announces More Than 1 Million Individuals Enrolled in Marketplace Coverage During SEP

The U.S. Department of Health and Human Services (HHS) [announced](#) more than a million individuals have signed up for health insurance through healthcare.gov during the 2021 Marketplace special enrollment period (SEP). This number reflects only people who enrolled in the federal exchange and does not include additional SEP enrollments in the 15 states that run their own exchange websites.

The SEP, which began on February 15, provides a new opportunity for individuals and families who buy their own coverage to enroll or switch plans. More than half of the SEP enrollments have taken place since expanded financial assistance under the American Rescue Plan Act became available on healthcare.gov on April 1.

HSA Deduction and HDHP Deductible Limits Released

The Internal Revenue Service (IRS) released [Rev. Proc. 2021-25](#) (May 10, 2021), establishing for 2022 limits on annual deductions to health savings accounts (HSAs) and limits on deductibles for high deductible health plans (HDHPs) linked to HSAs.

Annual Deduction Limit

For calendar year 2022, the annual limitations on deductions for HSAs are:

- *Individual with Self-Only Coverage*: \$3,650
- *Individual with Family Coverage*: \$7,300

High Deductible Health Plan

For calendar year 2022, a “high deductible health plan” is defined as a health plan with:

- *Annual Deductible*: Not less than \$1,400 for self-only coverage or \$2,800 for family coverage
- *Annual Out-of-Pocket Expenses (Deductibles, Co-Payments, and Other Amounts, but Not Premiums)*: Not exceeding \$7,050 for self-only coverage or \$14,100 for family coverage

Excepted Benefit HRA Inflation Adjusted Amount

For plan years beginning in 2022, the maximum amount that may be made newly available for the plan year for an excepted benefit health reimbursement arrangement is \$1,800. See Treas. Reg. § 54.9831-1(c)(3)(viii), (B)(3).

Variation from Maximum Out-of-Pocket Limits

Recall that the HDHP limits on out of pocket expenses and the maximum out-of-pocket limits under the Affordable Care Act (ACA) are NOT the same. The maximum out-of-pocket limits for the ACA in 2022 are \$8,700 for self-only coverage or \$17,400 for other than self-only coverage. See Notice of Benefit and Payment Parameters for 2022 Final Rule Part Two Fact Sheet. Plans should take this into consideration as they develop ACA products that they intend to be HDHPs.

State Issues

New York

Legislative

Active Health Care Bills With 4 Weeks Remaining in Legislative Session

The New York Health Act, legislation that would create a Single Payer health care system in New York, was not included on the agenda for this week’s Senate Health Committee meeting, thought to be the last of the session. That is significant, as the Committee Chair is a key sponsor. Single payer advocates are mobilizing supporters to push for a vote on the bill.

Meanwhile, the Realities of Single Payer, a coalition of organizations united in opposition to legislation to create a Single Payer health care system in New York, released a new [report](#) last week that found adopting a government-run, single payer system in New York would eliminate more than 160,000 jobs throughout the state.

Other active bills in the final four weeks of the session include:

- Co-pay accumulators -- requires insurance companies or pharmacy benefit managers to apply price reduction instruments for out-of-pocket expenses when calculating an insured individual’s cost-

sharing requirement, allowing consumers to apply drug coupons and discounts toward their annual out-of-pocket deductible costs.

- Mid-year formulary -- would prohibit health plans from making formulary changes except during the renewal and enrollment period leading up to the start of an employer's or individual's policy year.
- Step therapy -- prohibits the use of step therapy protocols in coverage for the diagnosis and treatment of mental health conditions. The bill is in the Assembly Insurance Committee.
- Opioid treatment copays – prohibits co-payments for treatment at an opioid treatment program.
- Consumer assistance program – creates an independent consumer assistance program to assist consumers with the filing of complaints and appeals.
- Mail order – amends current law to limit pharmacy mail order options for health care consumers.

Regulatory

New York Adopts CDC Mask Guidance

Gov. Cuomo announced that fully vaccinated individuals will no longer be required to wear a mask outdoors or in most indoor settings, effective Wednesday. That is also the day that most capacity restrictions will be lifted on restaurants, retail, offices and museums.

State Issues

Pennsylvania

Legislative

Nurse Licensure Compact Legislation Passes Senate, Moves to House for Consideration

Last week, the Pennsylvania Senate approved legislation, [Senate Bill 115](#), sponsored by Senator Lisa Boscola (D-Northampton), that will allow Pennsylvania to join 34 other states in the Nurse Licensure Compact, a multistate agreement that allows licensed nurses to practice in multiple states more freely.

The proposal addresses the ways the nation's health care delivery system is changing—requiring greater cooperation among states for nurse licensure and regulation—and creating the needed flexibility to support the health care workforce.

“The current system of duplicative licensure for nurses practicing in multiple states is cumbersome and redundant for both nurses and states,” the legislation says. “Uniformity of nurse licensure requirements throughout the states promotes public safety and public health benefits.”

The proposal would:

- Provide opportunities for interstate practice by nurses who meet uniform licensure requirements
- Facilitate the exchange of information between party states for nurse regulation, investigation, and adverse actions
- Promote compliance with the laws governing the practice of nursing in each jurisdiction
- Invest all party states with the authority to hold a nurse accountable for meeting all state practice laws in the state in which the patient is located at the time care is rendered through the mutual recognition of party state licenses
- Decrease redundancies in the consideration and issuance of nurse licenses

The bill now moves to the House for consideration where union groups are likely to seek amendments to mandate staffing reports by hospitals.

Why this matters: The legislation directly reflects recommendations from the Hospital & Healthsystem Association of Pennsylvania's Health Care Talent Task Force. During 2020, the task force issued a report expressing concerns about future workforce shortages and highlighting opportunities to reduce the administrative burdens on the caregivers within Pennsylvania's health care delivery system.

Hospitals strongly support this important legislation because Pennsylvania's participation in the Nurse Licensure Compact is a critical step to bolster the health care workforce and ensure outstanding care throughout the commonwealth.

The Pennsylvania General Assembly returns to session May 24.

The Delaware Legislature is in session May 18-20.

The New York Legislature is in session May 19 -20.

The West Virginia Legislature concluded session on April 10.

Congress

The U.S. House is in session May 17-20. The U.S. Senate is in session May 17-21.

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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