

Federal Issues

Legislative

Drug Pricing Deal Undergoes Review in Senate

Over the 4th of July recess, Senate Majority Leader Chuck Schumer (D-NY) began the Senate's procedural review of a [revised text](#) of a deal on drug pricing reform legislation, a key part of the slimmed down Senate reconciliation package previously known as Build Back Better.

Why This Matters: Although the fate of the broader reconciliation package remains unclear, all Senate Democrats appear to be on board with passing government price negotiations of prescription drugs for the first time.

The deal contains provisions for Medicare price negotiation and Part D reform that are similar to prior legislative proposals. It includes allowing Medicare negotiation of certain single-source Part B and Part D drugs; mandated rebates from manufacturers if their drug prices increase faster than inflation; a maximum annual out-of-pocket cap along with a monthly "smoothing" cap in Part D; different levels of liability under the Part D benefit for the government, manufacturers and plans; Part D premium stabilization

In this Issue:

Federal Issues

Legislative

- Drug Pricing Deal Undergoes Review in Senate

Regulatory

- CMS Releases 2023 Medicare Physician Fee Schedule Proposed Rule
- CMS Releases New Resources to Improve Oversight of Medicaid and CHIP Managed Care Programs
- President Biden Signs Executive Order on Protecting Access to Reproductive Health Care Services
- CMS Releases Findings from Implicit Bias Review of Innovation Center
- CMS Publishes Program Year 2021 Open Payments Data on Health Care Providers
- COVID-19 Updates

State Issues

New York

Regulatory

- DFS Notifies Insurers About Climate Risk Disclosure Survey

provisions; and \$0 cost sharing in Part D for recommended vaccines.

What's New: Notable changes from prior Senate proposals include:

- Specifying the number of drugs the Secretary must negotiate every year, rather than “up to” a required number;
- Applying new effective dates, including the first year the Part D negotiated price provisions take effect (2026 rather than 2025) and most Part D reforms (2024 rather than 2023);
- Removing insulin provisions such as a co-pay cap (the Senate is considering insulin proposals in separate legislation);
- Expanding the group of people eligible for full subsidies under the Part D low-income subsidy program; and
- Changing the level and duration of premium stabilization.
- No provisions impacting the commercial market were included as part of the release.

The Congressional Budget Office also [posted](#) the estimated budgetary effects of this legislation this week.

Pennsylvania

Legislative

- House Advances CHIP Choice Legislation
- Senate Advances Early Eye Drop Refill Legislation
- Governor Signs Mental Health and Substance Use Disorder Confidentiality Alignment Legislation
- General Assembly Passes State Budget for Fiscal Year 2022-2023
- Hospital Priorities in Fiscal Year 2022-2023 State Budget

Industry Trends

Policy / Market Trends

- New Federal Program for Low Income Access to Internet
- CBO Publishes Projections on Federal Subsidies for Health Insurance Coverage for People Under 65

Federal Issues

Regulatory

CMS Releases 2023 Medicare Physician Fee Schedule Proposed Rule

On July 7, 2022, the Centers for Medicare & Medicaid Services (CMS) [released](#) a proposed rule that updates Medicare payment policies, reimbursement rates, and quality reporting for services furnished under the Calendar Year (CY) Medicare Physician Fee Schedule (PFS) on or after January 1, 2023.

There are no Medicare Advantage specific provisions in this Proposed Rule. However, CMS did note they are considering policy and program levers that can advance health information exchange under the Trusted Exchange Framework and Common Agreement (TEFCA). Specifically, they are interested in opportunities to encourage exchange under TEFCA through CMS regulations for payers, including Medicare Advantage, Medicaid Managed Care, and CHIP issuers. We expect this to be first addressed by CMS in the “Interoperability and Prior Authorization (CMS-0057)” proposed rule targeted for release in September.

Why This Matters: For 2023, CMS is proposing a 4.4% cut to the conversion factor, which is the base rate under which all providers billing under the Medicare PFS are paid. The reduction is primarily due to the expiration of statutory add-on to rates.

- The proposed CY 2023 conversion factor is \$33.08, a decrease of \$1.53 from the CY 2022 PFS conversion factor of \$34.61. This includes the required budget neutrality adjustments and the required statutory update to the conversion factor for CY 2023 of 0%. The conversion factor is lower due to the expiration of the one-year 3% increase in CY 2022 mandated by the Protecting Medicare and American Farmers from Sequester Cuts Act.

The rule also proposes expansion of Medicare’s list of covered telehealth services; some of which CMS proposes to permanently add to the list of covered codes and others it proposes to extend coverage for through the end of CY 2023. These include services permitted under current COVID-19 waivers that Congress legislatively extended for 151 days post the expiration of the COVID-19 public health emergency (PHE). The rule includes several proposals aimed at increasing access to behavioral health services, including delaying the in-person visit requirement for behavioral health services furnished via telehealth for 151 days post-PHE.

For the Medicare Shared Savings Program, CMS makes several technical proposals [summarized here](#). Of interest to MA plans is the commentary on HCC risk model coding intensity. CMS is proposing a positive 3 percent cap (after accounting for changes in demographic risk scores) similar to the risk score cap for the ACO Reach Program. CMS believes that “ACOs would be much less likely to have prospective HCC risk ratios for ESRD, disabled, and aged/dual eligible Medicare enrollment types capped under this proposed policy which would improve the incentives for treating these medically complex, high-cost populations. At the same time, we [CMS] believe that this proposed policy would continue to be protective of the Trust Funds by continuing to limit incentives for coding intensity.”

The rule also continues to implement the Merit-Based Incentive Payment System (MIPS) Value Pathways (MVPs), subsets of MIPS reporting requirements, that aim to align and connect measures and activities

across the quality, cost, and improvement activities performance categories of MIPS for different specialties or conditions. CMS proposes five additional MVPs in the rule. CMS also included several requests for information addressing health equity, progressing to digital quality measurement, and advancing the Trusted Exchange Framework and Common Agreement (TEFCA).

CMS invites comment for 60 days (Deadline - Sept 6) for these and other policy proposals and will likely finalize the Physician Fee Schedule in the Fall.

CMS Releases New Resources to Improve Oversight of Medicaid and CHIP Managed Care Programs

CMS [released](#) a suite of new resources to improve Centers for Medicare & Medicaid Services (CMS) and state oversight of Medicaid and Children's Health Insurance Program (CHIP) managed care programs. These resources include:

- A web-based reporting portal for the collection of required managed care reports
- A standardized medical loss ratio reporting template, which states will be required to use for all rate certification packages submitted on or after Oct. 1, 2022
- A new, standardized adequacy and access assurances report, which states will be required to use for all adequacy and access reports submitted on or after Oct. 1, 2022
- A toolkit for managed long-term services and supports (MLTSS) access monitoring

With the [release](#), CMS also clarifies requirements around reporting transparency and public availability of managed care reports.

President Biden Signs Executive Order on Protecting Access to Reproductive Health Care Services

President Biden signed an [executive order \(EO\)](#) on Protecting Access to Reproductive Health Care Services. A fact sheet is available [here](#).

The EO focuses on the following areas:

- **Access to Services:** Directs the Department of Health and Human Services (HHS) to safeguard access to reproductive health care services, including abortion and contraception by protecting and expanding access to abortion care including medication, ensuring pregnant women and those experiencing pregnancy loss have access to emergency medical care rights and protections, and expanding access to reproductive health services.
- **Consumer Privacy:** Asks the Chair of the Federal Trade Commission (FTC) to consider taking steps to protect consumer privacy when seeking information about reproductive health care services

and directs the Secretary of HHS, in consultation with the FTC and Attorney General to consider options to address deceptive or fraudulent practices and protect sensitive information.

- **Promoting Safety:** Ensure safety of patients, providers, and third parties and protect security of entities providing, dispensing, or delivering reproductive health care services.
 - **Coordinating Federal Efforts:** Directs HHS and the White House Gender Policy Council to establish and lead an interagency Task Force on Reproductive Health Care Access to policy making and program development and directs the Attorney General to provide technical assistance to states affording legal protection to out-of-state patients and providers who offer legal reproductive health care.
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CMS Releases Findings from Implicit Bias Review of Innovation Center

The Centers for Medicare and Medicaid Services Innovation Center (CMMI) [published a blog post in Health Affairs](#) detailing findings from an assessment of potential implicit bias in three CMMI models: the Kidney Care Choices Model, the Comprehensive Care for Joint Replacement Model and the Million Hearts Cardiovascular Risk Reduction Model. The assessment found that the use of certain risk-assessment and screening tools, provider tools and payment design and risk-adjustment algorithms had led to the exclusion of some groups of beneficiaries from these models. CMMI also outlines initial steps taken to address these sources of bias for ongoing models and describes plans to screen for and mitigate bias in future models.

CMS Publishes Program Year 2021 Open Payments Data on Health Care Providers

Last week, CMS [published](#) Program Year (PY) 2021 Open Payments data to publicly disclose the financial relationships between applicable manufacturers and group purchasing organizations (GPOs) and certain health care providers. This release reflects a total of 12.1 million records and \$10.9 billion in publishable payments or transfers of value made to covered health care providers during PY 2021.

The Open Payments data promotes transparency by allowing anyone to search and access information about payments and other transfers of value such as gifts, honoraria, consulting fees, research grants, travel reimbursements, and other payments and transfers of value that reporting entities such as drug or device manufacturers provide to covered health care providers. This information also includes ownership and investment interests held by physicians or their immediate family members. Reporting entities reported publishable payments to covered recipients during PY 2021 in three major categories:

- General Payments: \$2.55 billion
- Research Payments: \$7.09 billion
- Ownership and Investment Interest: \$1.26 million

COVID-19 Updates

The [U.S. Food and Drug Administration \(FDA\)](#) revised the [Emergency Use Authorization \(EUA\)](#) for Pfizer's Paxlovid treatment of mild-to-moderate COVID-19 infection in eligible patients. This action allows state-licensed pharmacists, including [Test-to-Treat sites](#), to prescribe Paxlovid with certain limitations (described below). Community pharmacies not already participating as a Test-to-Treat site can decide if or how they will offer this service to patients.

Patients testing positive for COVID-19 who are seeking to determine their eligibility for receiving Paxlovid from state-licensed pharmacists should bring the following information with them to ensure their pharmacist has sufficient information to determine their eligibility:

- Electronic or printed health records less than 12 months old, including the most recent reports of laboratory blood work for the state-licensed pharmacist to review for kidney or liver problems. State-licensed pharmacists could also receive this information through a consult with the patient's health care provider.
- A list of all medications they are taking, including over-the-counter medications so the state-licensed pharmacist can screen for drugs with potentially serious interactions with Paxlovid.

Furthermore, under the limitations outlined in the FDA authorization, state licensed pharmacists should refer patients for further clinical evaluation with a practitioner if any of the following apply:

- Sufficient information is not available to assess renal and hepatic function.
- Sufficient information is not available to assess for a potential drug interaction.
- Modification of other medications is needed due to a potential drug interaction.
- Paxlovid is not an appropriate therapeutic option based on the current [Fact Sheet for Healthcare Providers](#) or due to potential drug interactions for which recommended monitoring would not be feasible.

Additional information on COVID-19 treatment can be found here:

- [Coronavirus Treatment Acceleration Program \(CTAP\)](#)
- [Test to Treat Locator](#)
- [COVID-19 Therapeutics Locator](#)

State Issues

New York

Regulatory

DFS Notifies Insurers About Climate Risk Disclosure Survey

Last week the Department of Financial Services (DFS) sent a notice to New York domestic insurers — including health insurers — relating to the NAIC Climate Risk Disclosure Survey and a Request for Information on climate-related governance and organizational structure. The RFI is related to the November 2021 Guidance for New York Domestic Insurers on Managing the Financial Risks from Climate Change, which details the Department’s supervisory expectations for insurers’ management and disclosure of their financial risks from climate change. DFS indicated that it intends to use the NAIC Survey to verify compliance with the Guidance for those New York domestic insurers with annual countrywide premiums of over \$100 million that DFS is responsible for contacting, and the RFI for the rest of the insurers. Both the survey responses and the RFI are due on November 30, 2022.

State Issues

Pennsylvania

Legislative

House Advances CHIP Choice Legislation

On Wednesday, July 6, the House advanced [Senate Bill 1235](#) (DiSanto, R-Dauphin). Senate Bill 1235 would prohibit the Pennsylvania Department of Human Services from developing or utilizing bidding or service zones that limit a health service corporation or hospital plan corporation contractor from submitting a bid for CHIP.

Senate Bill 1235 was presented to the Governor for signature.

Why This Matters: Highmark expressed support for advancing Senate Bill 1235, which would provide a path for certain families to maintain CHIP coverage without disruption.

Senate Advances Early Eye Drop Refill Legislation

On Thursday, July 7, the Senate advanced [Senate Bill 1201](#) (Pittman, R-Indiana). Senate Bill 1201 would provide coverage of prescription eye drops refills if the refill is requested:

- Between 21 and 30 days after the original date for 30 day supplies or after the insured received the most recent refill;
- Between 42 and 60 days after the original date for 60 day supplies or after the insured received the most recent refill; and
- Between 63 and 90 days after the original date for 90 day supplies or after the insured received the most recent refill.

Senate Bill 1201 was referred to the House Insurance Committee for consideration.

Governor Signs Mental Health and Substance Use Disorder Confidentiality Alignment Legislation

On Thursday, July 7, the Governor signed the following bills:

- [House Bill 1561](#) (Farry, R-Bucks) updates the Mental Health Procedures Act to bring PA into alignment with HIPAA standards to permit providers, facilities, and health plans to share appropriate patient mental health and substance use disorder-related information. House Bill 1561 is Act 32 of 2022.
- [House Bill 1563](#) (Cutler, R-Lancaster) updates the Drug and Alcohol Abuse Act to bring PA into alignment with HIPAA standards to permit providers, facilities, and health plans to share appropriate patient mental health and substance use disorder-related information. House Bill 1563 is Act 33 of 2022.

Why This Matters: Highmark and AHN support legislation that brings PA into alignment with current HIPAA standards which would permit providers, facilities, and health plans to collaboratively share appropriate patient mental health and substance use disorder-related information, in accordance with HIPAA, to provide more effective care.

General Assembly Passes State Budget for Fiscal Year 2022-2023

On Friday, July 8, the General Assembly approved a \$45.2 billion state budget for FY 2022-2023. The budget offers increases in childcare and K-12 education, appropriates approximately \$2.2 billion in American Rescue Plan Act (ARPA) funds, and cuts the corporate net income tax by 5% in a tiered approach over the next nine years.

Hospital Priorities in Fiscal Year 2022–2023 State Budget

Last week, the General Assembly finalized a \$45.2 billion budget for the 2022–2023 state fiscal year. The budget includes \$2.4 billion in federal relief dollars. The governor is expected to sign the budget legislation.

The commonwealth identified \$2.1 billion of the General Fund's surplus to be deposited in the state's Rainy Day fund, increasing the fund's total to \$5 billion. Another \$3.6 billion was set aside to be used at a later time.

Relevant Updates on Key Hospital Priorities:

Behavioral health—Hospitals advocated for a multifaceted plan to address the behavioral health crisis and relieve the strain on emergency departments caused by a lack of services. The cornerstone of this plan was an increase in county mental health funding to bolster community and home-based behavioral health services.

The budget includes:

- A \$42.6 million increase in the county mental health line
- An additional \$100 million in one-time, federal dollars from the American Rescue Plan Act (ARPA) set aside to support adult behavioral health. Funding will be allocated by future legislation with input from a blue-ribbon commission, which will include a hospital designee. The commission will meet with stakeholders, including hospitals, and recommend allocation of funding in the following areas:
 - ✓ Delivery of services by telemedicine

- ✓ Behavioral health rates, network adequacy, and mental health payment parity
- ✓ Workforce development and retention
- ✓ Expansion of certified peer support specialist services and peer-run services
- ✓ Development and provision of crisis services
- ✓ Integration of behavioral health and substance use disorder treatment
- ✓ Cultural competencies when providing behavioral health care
- ✓ The impact of social determinants of health on behavioral health
- ✓ The intersection of behavioral health and the criminal justice system
- ✓ Establishing an integrated care model that can deliver timely psychiatric care in a primary care setting
- \$100 million from “Ready to Learn” block grant for school-based mental health, including grants to school districts to train and fund mental health professionals, contract with providers, and other activities

Why This Matters: These investments are significant steps to support hospitals’ needs related to increasing behavioral health care and reducing emergency department and acute care boarding.

Workforce—The budget makes investments to support the health care workforce, including:

- \$35 million additional allocation of ARPA funds for nurse student loan forgiveness, raising the state’s total nurse loan forgiveness investment this year to \$50 million
- \$2.5 million increase to the Primary Health Care Practitioner Program

Medicaid supplemental budget lines—The budget fully funds Medicaid supplemental budget lines for burn centers, critical access hospitals, obstetric/neonatal services, and trauma centers. Supplemental funding includes:

- Burn Centers: \$4.4 million
- Critical Access Hospitals: \$13 million
- Obstetric and Neonatal Services: \$3.7 million
- Trauma Centers: \$8.7 million

Additional investments—The budget makes a number of other investments relevant to the health care community:

- \$150 million to assist nursing homes specifically with costs associated with new regulatory staffing requirements
- \$250 million in ARPA funds to support long-term living programs, which will help alleviate stress on the continuum of care
- \$20 million increase in supplementary payments to personal care homes, augmenting capacity for post-acute care placements
- \$4.2 million increase to support local health departments
- \$23 million to satisfy Children’s Health Insurance Program arrearages rather than terminate participants
- \$278.8 million for broadband capital projects

New commission—The school code bill creates a commission on education and economic competitiveness to consider the needs of major industries, including health care.

Language not included—The budget does not include language proposed during budget negotiations to create a duplicative and burdensome outcomes-based hospital program—as well as arbitrary reductions in

Medicaid managed care capitated rates—which could have led to possible reductions in hospital payments. Additionally, the budget does not include a mandatory bond program that was proposed.

The General Assembly passed and the governor is expected to sign accompanying fiscal and school code bills that provide implementing language for the budget.

The governor vetoed the human services code. Relevant policies that were included in the human services code and remain unresolved include, among other provisions: requirements providing mileage limitations in the establishment of outpatient emergency departments under the hospital innovation guidance issued earlier this year; and a public awareness campaign related to COVID-19 and mental health, making resources available to first responders, health care workers, and other front-line workers.

Resolved were provisions related to appropriations for long-term and personal care, which the General Assembly subsequently amended into the fiscal code.

Non-budget Priorities: In the days leading up to the budget passage, the General Assembly extended health care waivers and flexibilities through October and passed several bills related to hospital priorities, including:

- [House Bill 2604](#), offering flexibility around how facility names appear on health care ID badges, allowing health systems and registered names with the Department of State to be used instead of just licensed facilities
- House Bills [1561](#) and [1563](#), aligning state behavioral health and substance use disorder information-sharing laws with HIPAA and other federal regulations
- [House Bill 1868](#), expediting professional licensure for veterans and military spouses
- [House Bill 2419](#), allowing for greater flexibility to provide psychiatric services via telehealth
- [House Bill 2401](#), allowing certified registered nurse practitioners and physician assistants to order and oversee orders and registered nurses to remotely supervise visits in certain circumstances
- [House Bill 2032](#), clarifying that when a person requests to remain anonymous when seeking medical care for sexual assault, the health care provider is not required to report the assault injuries under state law unless the patient has suffered a wound injury that caused death, serious bodily injury, or was inflicted by a deadly weapon

In addition, the Senate passed [Senate Bill 225](#), which reforms the processes for prior authorization and step-therapy protocol. The bill now advances to the House for consideration this fall.

Industry Trends

Policy / Market Trends

New Federal Program for Low Income Access to Internet

A new [federal program](#) is available to help low-income individuals in accessing high-speed internet, including access to critical telehealth services. The Bipartisan Infrastructure Law's Affordable Connectivity Program (ACP) provides eligible households \$30 per month (or \$75 per month on Tribal lands) toward their internet service plan.

About 48 million households, or nearly 40% of households in the country, qualify for the ACP. Households are eligible if their income is at or below 200% of the Federal Poverty Level, or if they participate in certain other federal assistance programs, including Medicaid.

Certain internet providers are offering high-speed internet plans that are fully covered by the ACP subsidy; eligible families who claim their ACP benefit and select these internet plans can get high-speed internet at no out-of-pocket cost. Eligible families can also choose to apply the subsidy to other internet plans if they wish.

Additional information, including eligibility details and a sign-up opportunity to become an outreach partner, is available on the Federal Communications Commission's (FCC) [website](#). The website for enrollees looking for more information or to apply can be found [here](#).

CBO Publishes Projections on Federal Subsidies for Health Insurance Coverage for People Under 65

The Congressional Budget Office (CBO) published its annual report projecting federal subsidies for health insurance coverage for people under age 65 for the next decade. CBO projects Medicaid and CHIP will account for 42% of annual subsidies between 2022 and 2031. The report also highlights the impact of public health emergency (PHE) policies on Medicaid and the Marketplace. CBO estimates that 12.9 million people are currently enrolled in Medicaid because of continuous enrollment provisions and will likely lose Medicaid coverage when these provisions expire. [Read More](#)

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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