

Federal Issues

Legislative

U.S. House Passes Bipartisan Mental Health Package, ARPA-H

The U.S. House on Wednesday [passed](#) legislation reauthorizing a number of priority mental health programs as well as a bill creating a new federal agency designed to foster health innovation.

Why this matters: Despite bipartisanship on health care issues being difficult to find in an election year, these two initiatives have a good chance of becoming law. Several committees of jurisdiction across Capitol Hill are working on complimentary mental health workstreams that will likely be rolled into a larger package later in the year.

The [Restoring Hope for Mental Health and Well-Being Act](#), includes reauthorization of a number of expiring initiatives, including programs to address suicides through a new hotline as well as mental health for maternal care and in Native populations. In addition, the legislation includes the advancement of the Collaborative Care Model, integrating mental health care into primary care settings, as well as a [requirement](#) that insurers that are self-funded and do not offer federal government plans to comply with laws

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requiring the same coverage for mental health care as for medical care.

Also passed Wednesday, the [Advanced Research Projects Agency–Health \(ARPA-H\) Act](#) authorizes a new federal agency that would accelerate health and medical innovation by investing in high-risk, high-reward research. Originally proposed in President Biden’s fiscal year 2022 budget request, the spending bill signed by the president on March 15 provides \$1 billion for the Department of Health and Human Services to establish the agency.

Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ) and Health Subcommittee Chairwoman Anna G. Eshoo (D-CA), said in a [statement](#) that “the pivotal investments we’re making today will become the biomedical breakthroughs of tomorrow. The establishment of ARPA-H signals a promising future with new cures and treatments as well as cutting-edge tests to detect illnesses sooner.” Committee Republicans also hailed the bill’s passage, with Republican Leader Cathy McMorris Rodgers (R-WA) and Health Subcommittee Republican Leader Brett Guthrie (R-KY) issuing a [statement](#) saying it promotes “the development of transformative health technologies by supporting high-risk, high-reward biomedical projects not being met by existing Federal programs or the private sector.”

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Coalition Urges Congress to Extend Enhanced ACA Premium Tax Credits

AHIP [joined](#) the nations' leading organizations from across the health care landscape to call on Congress to extend the expanded Affordable Care Act (ACA) health care premium tax credits and address the Medicaid coverage gap.

The groups, including AHIP, the American Cancer Society Cancer Action Network, AARP, American Heart Association, American Medical Association, American Nurses Association, National Association of Community Health Centers, and the National Rural Health Association warned Congress about the consequences of “premium shock” when premium tax credits end.

Why this matters: Premiums could increase by double digits, forcing at least 3 million more Americans to lose insurance coverage. This loss could have a lasting impact beyond 2023, destabilizing the market and further driving up health care costs.

The full letter sent to Congress by these patient, health care provider, and insurer groups can be found [here](#).

Senate Introduces Insulin Co-Pay Cap Bill

Sens. Jeanne Shaheen (D-NH) and Susan Collins (R-ME) [introduced](#) the Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act. The bill would require that insulin manufacturers who agree to charge no more than 2021 Medicare Part D negotiated prices for their products and to limit their future price increases to inflationary adjustments will enjoy “certified” status that would guarantee coverage of their products and restrict PBMs, group, individual market, Medicare Part D and Medicare Advantage plans from imposing prior authorization or other utilization management restrictions on them.

Health insurance providers and PBMs would be prohibited from negotiating rebates for certified insulins and would be required to waive any deductible and limit cost-sharing to the lesser of either \$35 per month or 25% of the list price. Senate Majority Leader Chuck Schumer (D-NY) [issued](#) a press release stating that he will put the INSULIN Act on the Senate floor “very soon.” The House of Representatives passed insulin cap legislation, [H.R. 6833](#), in March.

Sens. Collins and Shaheen also issued a [one-pager](#) and a section-by-section [summary](#) on the INSULIN Act. Text of the legislation is available [here](#).

Insurer Perspective: AHIP issued a statement on the Senate legislation:

“Every American deserves access to the medications they need at an affordable price, including the more than 8 million Americans who rely on life-saving insulin.

“While we support efforts to make prescription drugs more affordable for everyone, this draft legislation raises serious concerns. We have made real strides in improving insulin prices for patients through private market competition and innovation, and the market continues to evolve. We should build on those achievements as a foundation rather than undermine successful, competitive private-market solutions.

“AHIP supports real solutions that leverage private market solutions to deliver affordable drugs for patients,

address the lack of transparency in how pharmaceutical companies set and increase prices, and deliver lower health insurance premiums and out of pocket costs for all consumers. We will continue to work with Congress and the Administration as they consider this bill.”

Federal Issues

Regulatory

HHS Issues Fact Sheet and Guidance Related to ARPA Subsidies

The Departments of Health and Human Services [published](#) a new fact sheet on what will happen if Congress does not act to extend American Rescue Plan Act (ARPA) subsidies.

Why this matters: The fact sheet emphasizes coverage gains resulting from ARPA subsidies and highlights HHS projections that approximately 3 million Americans could lose health insurance coverage and 10 million Americans will face significantly higher out-of-pocket premiums due to reduced financial assistance.

- Due to the uncertainty around continued funding for ARPA subsidies, the Centers for Medicare and Medicaid Services (CMS) issued [guidance](#) providing an enforcement safe harbor related to renewal notices qualified health plan (QHP) issuers will send enrollees for plan year 2023. In response to AHIP advocacy, this safe harbor will allow issuers to omit information on advance payments of premium tax credits (APTC) and premiums from renewal notices for plan year 2023. This flexibility will allow issuers to avoid sending consumers misleading information about financial assistance if ARPA subsidies are not extended.

This [guidance](#) provides individual market qualified health plan (QHP) issuers with flexibility, if states permit, to use modified federal standard notices of product discontinuation and renewal in connection with the open enrollment period for the 2023 benefit year. Instead of providing renewing members with an estimated 2023 net premium and tax credit amount based on enrollees' 2022 ARPA tax credits, issuers may direct enrollees to their exchange to view their 2023 premiums and tax credits. If the enhanced ARPA tax credits are extended, CMS encourages issuers to include estimated net premium and tax credit amounts in their notices, but the safe harbor remains in place regardless.

CMS is also extending the deadline to send discontinuation notices to November 1, consistent with previous years' safe harbors.

2023 Home Health PPS and Home Infusion Therapy Proposed Rule

CMS [issued](#) the CY 2023 Home Health Prospective Payment System (HH PPS) Rate Update proposed rule, which would update Medicare payment policies and rates for home health agencies (HHAs). CMS estimates that Medicare payments to HHAs in CY 2023 would decrease in the aggregate by - 4.2%, or - \$810 million compared to CY 2022, based on the proposed policies. Additionally, CMS is proposing to:

- Apply a -7.69% permanent prospective payment adjustment to the home health 30-day period payment rate to account for any increases or decreases in aggregate expenditures.
- Update the baseline years in the Expanded Home Health Value-Based Purchasing (HHVBP) Model.

CMS is soliciting comments on how best to implement a temporary payment adjustment for CYs 2020 and 2021. As well as seeking feedback on the collection of telehealth data on home health claims, the health equity measure development for the Home Health QRP and the application of health equity in the Expanded HHVBP Model's scoring and payment methodologies.

Comments are due August 16.

2023 ESRD PPS Proposed Rule

The Centers for Medicare & Medicaid Services (CMS) [issued](#) a proposed rule that proposes to update payment rates and policies under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for renal dialysis services furnished to Medicare beneficiaries on or after January 1, 2023. For 2023, Medicare expects to pay \$8.2 billion to approximately 7,800 ESRD facilities for furnishing renal dialysis services. The proposed base rate is \$264.09, which would be an increase of \$6.19 to the current base rate of \$257.90.

This rule also proposes the following:

- To update the Acute Kidney Injury (AKI) dialysis payment rate for Calendar Year (CY) 2023 to equal the CY 2023 ESRD PPS base rate and to apply the CY 2023 wage index.
- To continue to collect and publicly report all ESRD Quality Incentive Program (QIP) measures while pausing the use of certain measures for scoring and payment adjustment purposes because CMS has determined the COVID-19 pandemic has significantly affected the validity and reliability of the measures and resulting performance scores.
- Two payment adjustments to the ESRD Treatment Choices Model.

CMS also requests information for ESRD QIP regarding quality indicators for home dialysis, measuring health care quality disparities and two social drivers of health measures. A full overview of the proposed changes are available in the fact sheet below.

The proposed rule will be published in the Federal Register on Tuesday, June 28 and comments will be due 60 days after this filing.

CMS Announces RADV Delays

CMS published an announcement that is [delaying 2020 benefit year HHS-RADV results](#). As a result, CMS will also delay the release of the Summary Report of 2019 and 2020 Benefit Year HHS-RADV Adjustments to Risk Adjustment Transfers, and CMS will not initiate the collection and distribution of these adjusted transfer amounts as originally planned in Summer 2022. CMS intends to release the Summary Report of 2019 and 2020 Benefit Year HHS-RADV Adjustments to Risk Adjustment Transfers in Fall 2022 and initiate the collection and distribution of these adjusted transfer amounts shortly thereafter. Since these amounts will not be available until after August 15, these HHS-RADV adjustments to 2020 benefit year risk adjustment transfers should be reflected on 2022 MLR reports (reports due July 31, 2023) instead of the 2021 MLR reports (reports due July 31, 2022).

State Issues

Delaware

Legislative

Legislature Set to Wrap Up in Final Week of Session

Lawmakers will bring the 151st General Assembly to a close on June 30. Bills of interest that have crossed over from chamber of origin and are expected to be brought up for final consideration are as follows:

- [SB 267](#), **Coupon Accumulator**: Requires that third-party cost-sharing assistance utilized by patients is applied toward the enrollee's health insurance deductibles and any out-of-pocket limits. This bill applies to both carriers and pharmacy benefits managers with an effective date of January 1, 2024.
- [SB 316 w/ SA 1](#), **Diabetes Supply Cap**: Caps supplies at \$35 per month. Highmark requested and was granted the removal of "pharmaceutical agents" from the definition of "diabetes supplies" from the original draft.
- [HB 455](#), **Relating to Women's Reproductive Health**: Concerns have been raised over mid-level providers performing surgical abortions without additional training, possible amendment under consideration.
- [HB 303 w/ HA 2](#): Requires coverage for an annual behavioral health wellness check.
- **The EOB suppression bills**, [HB 400](#) (originally [HB 261](#)) have been stricken by the sponsor due to concerns raised over the impact this legislation could have on services provided by school-based health centers. It is expected to be reintroduced next year.

Regulatory

New Carriers to Delaware's Health Insurance Marketplace

Insurance Commissioner Trinidad Navarro announced that two additional carriers will enter Delaware's Health Insurance Marketplace for plan year 2023. AmeriHealth Caritas and Aetna CVS Health will join Highmark Blue Cross Blue Shield Delaware in offering coverage. To read the full press announcement [click here](#).

State Issues

New York

Regulatory

HPA Issues Policy Brief on 2023 Rates

The Department of Financial Services earlier this month posted plans' 2023 premium rate applications, with a proposed average rate increase of 18.7% for the individual market and 16.5% for small group policies. To provide context for the rate requests, the NY Health Plan Association (HPA) issued a new policy brief, *Health Insurance 101: Understanding Health Care Premiums*, examining the drivers of rising health care costs affecting health insurance premiums. The issue brief highlights the following key factors:

- Costs related to **COVID-19** including testing, treatment and vaccines, as well as care deferred during the pandemic;
- Higher prices that pharmaceutical companies are charging for **prescription drugs**;
- Increases in prices charged by **hospitals, physicians and other providers**;
- **Mandated benefits**, including several new mandates passed during the 2022 legislative session;
- **Taxes on health insurance**, which add over \$6.5 billion annually to the cost of health insurance, increasing the annual premium for the average family buying a policy in New York by more than \$1,000; and
- The potential **loss of federal subsidies** included in the American Rescue Plan Act that have helped to reduce premiums for more than 138,000 New Yorkers, which are set to expire at the end of 2022.

HPA President and CEO Eric Linzer reiterated these points in a number of media interviews and discussed the issue at length on the statewide radio program, [Capitol Pressroom](#). HPA will continue sharing the issue brief with policymakers, stressing the point that it is critical that the final premium rates approval by the state fully reflect the factors contributing to the growth in health care costs.

AG Hearing on Mental Health “Crisis”

State Attorney General Letitia James convened a hearing last week to examine New York's mental health care system, which she described as in “crisis,” saying she wants to look at possible reforms as well as future investigations into what the AG called “allegations of inadequate mental health treatment.” Numerous advocates, doctors and public officials spoke at the hours-long hearing, with the focus of most of the comments on lack of a sufficient number of inpatient psychiatric beds, community-based providers, and crisis stabilization programs. When comments were made regarding insurance, it was usually about inadequate reimbursement – primarily commercial insurance but some included Medicaid managed care as well – which was universally described as “woefully inadequate.” Parity came up a number of times, normally in the context of reimbursement, but also in the context of the violations that have been posted on the Department of Health website. Discharge planning also came up repeatedly as a significant problem where there is widespread failure on the part of the hospitals. It is not clear what next steps the AG is planning.

Maternity Care Data Request Being Revised

DFS convened a call with plan associations to review the draft 308 letter and spreadsheets that will be used to collect plan data for the maternity care report that DFS and DOH must issue by the end of the year. DFS staff outlined several changes that will be made to the data collection tool and reviewed numerous questions that the associations had received from plans. Once compiled, the Q & A will be shared with plans. Staff indicated it is aiming to get revised materials out to plans after the July 4th holiday.

State Issues

Pennsylvania

Legislative

Senate Advances Testing and Coverage for Lyme Disease

On Wednesday, June 22, the Senate unanimously advanced [Senate Bill 1188](#) (Brooks, R-Crawford). Senate Bill 1188 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.

Senate Bill 1188 was referred to the House Health Committee for consideration.

Why this matters: Highmark and AHN expressed opposition with advancing Senate Bill 1188. 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. Highmark and AHN will continue to oppose and monitor Senate Bill 1188.

Senate Committee Advances Mental Health and Substance Use Disorder Confidentiality Alignment Legislation

On Wednesday, June 22, the Senate Health and Human Services Committee advanced 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 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.

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.

Senate Advances Prior Authorization Legislation

On Wednesday, June 22, the Senate advanced [Senate Bill 225](#) (Phillips-Hill, R-York) with amendment [A05018](#), on second consideration. Amendment A05018 seeks to streamline and standardize the process for prior authorization and step therapy considerations for insurers, MCO's and contractors.

Industry Trends

Policy / Market Trends

Supreme Court Issues Opinion in *Dobbs v. Jackson Women’s Health Organization* Overturning *Roe* and *Casey*

The U.S. Supreme Court issued a decision in *Dobbs v. Jackson Women’s Health Organization* [19-1392 Dobbs v. Jackson Women’s Health Organization \(06/24/2022\) \(supremecourt.gov\)](#) upholding Mississippi’s 15-week abortion ban and overturning the constitutional right first established in *Roe vs. Wade*. The court held: “The Constitution does not confer a right to abortion; *Roe* and *Casey* are overruled; and the authority to regulate abortion is returned to the people and their elected representatives.”

The decision to uphold the Mississippi ban was 6-3. Chief Justice Roberts did not join the other five justices in the majority on the issue of whether *Roe* was wrongly decided but concurred in the result.

In a public address, President Biden directed his Administration to take steps to ensure availability of abortion medication to the greatest extent possible and to protect interstate travel for women seeking abortions and access to FDA-approved medications for abortion and contraception. The President also announced that additional executive actions to protect abortion access will be forthcoming and released a [Fact Sheet](#).

SCOTUS Rejects DaVita’s Arguments that Employer Plan’s Limited Benefit for Outpatient Dialysis Violates Medicare Secondary Payer Statute

The Supreme Court issued a 7-2 [opinion](#) in [Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc.](#) rejecting DaVita’s arguments that an employer health benefit plan discriminates against patients with end-stage kidney disease by reimbursing them at low rates in hopes they would switch to Medicare. The Court based its decision, in part, on the language of the relevant statute, which indicates that a plan “may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan.”

The opinion also rejected DaVita’s argument “that the statute authorizes liability . . . if [a] limitation on benefits has a disparate impact on individuals with end-stage renal disease.” This position “would ultimately require group health plans to maintain some (undefined) minimum level of benefits for outpatient dialysis,” something Congress plainly did not intend.

SCOTUS Declines to Hear *United v. Becerra* on Medicare Overpayments

The U.S. Supreme Court [denied](#) United’s cert. petition seeking review of the D.C. Circuit’s decision in a challenge to the Medicare Overpayment Rule (*UnitedHealthcare v. Becerra*).

The district court initially ruled in United’s favor in 2018, finding that the Overpayment Rule violated the statutory requirement of “actuarial equivalence” and constituted a departure from prior policy without adequate explanation. Based, in part, on the separate statutory locations of the Overpayment Rule and the “actuarial equivalence” requirement, the D.C. Circuit reversed the district court’s decision in August of last year.

Why this matters: With the Supreme Court’s decision not to consider the matter, the D.C. Circuit’s decision in favor of the government will remain in place.

Study: Health Savings Accounts No Longer Promote Consumer Cost-Consciousness

A Health Affairs [study](#) argues HSAs no longer appreciably achieve cost-consciousness among consumers because HSA cost-sharing levels are much more generous than when HSAs were first originated. Government-set minimum deductibles and maximum OOP amounts for HSA plans are indexed to general inflation rather than to health care cost growth, which has resulted in increasingly generous cost-sharing, especially when compared to non-HSA-qualified plans. Indeed, people who have HDHPs with HSAs are becoming less likely than others with private insurance to report financial barriers to care. The authors opine that promised gains in efficiency from HSAs have not been borne out, so it is difficult to justify maintaining the federal tax break granted such coverage.

Drivers of Health Insurance Premium Increases

The American Academy of Actuaries (AAA) released an [issue brief](#) laying out the factors underlying premium rate setting and highlighting the major components driving premium changes in 2023. Key points include the following:

- Although COVID-19-related costs may be more predictable than in the early stages of the pandemic, there is still uncertainty regarding whether new variants will evade immunity and cause a resumption in more serious health problems.
 - The expiration of the ARPA enhanced premium subsidies will likely cause a decline in enrollment and a worsening of the risk pool.
 - Medicaid redeterminations could cause an influx of people into the individual market, potentially improving the risk pool and lowering the premiums somewhat. Any effects would be less than those caused by the expiration of ARPA subsidies.
 - Provider contract rates lag inflation because they are set in advance and may cover a multi-year period. Some inflation will likely be reflected in contract rates taking effect in late 2022 and early 2023. In addition, workforce shortages could put upward pressure on provider payment rates.
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100 Million People in America Are Saddled With Health Care Debt

A June 16 Kaiser Health News [article](#) reports more than 100 million people in American, including 41 million adults, are carrying health care debt. The data, which come from a nationwide poll conducted by the Kaiser Family Foundations, as well as analyses of credit bureau, hospital billing and credit card data by the Urban Institute and others, also reveal a quarter of adults with health care debt over more than \$5,000, and about 20% with any amount of debt said they don't expect to ever pay it off. Additionally, about one in seven people with debt said they've been denied access to a hospital or other provider because of unpaid bills.

Infant Formula Shortage Update

The Biden Administration [announced](#) three new Operation Fly formula missions. By the end of this weekend, they will have completed 32 flights and imported the equivalent of 19 million bottle so infant formula. The Administration noted in a briefing that they are ramping up domestic production, increasing imports, and enhancing WIC flexibilities to address the shortage.

The FDA's most recent update on efforts to increase supply and availability of safe and nutrition infant formula can be found [here](#).

The Administration has created resources with public health guidance and related information for public use. The resources include the most up-to-date information on infant formula, including specialty formula. Please see below for these resources:

- [S. Department of Health and Human Services \(HHS\) Infant Formula website](#)
- [HHS Infant Formula Social Media Toolkit](#)
- [White House Fact Sheet on the Biden-Harris Administration's Progress Addressing the Infant Formula Shortage](#)
- [White House Infant Formula website](#)
- [North American Society of Pediatric Gastroenterology, Hepatology & Nutrition \(NASPGHAN\) Tools for Infants and Children Affected by Formula Shortages](#)

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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