

Federal Issues

Legislative

Senators Release Competing Prescription Drug Proposals

On Tuesday, Senate Finance Committee Chairman Ron Wyden (D-OR) released [principles](#) for legislation to reform the U.S. prescription drug market, which are expected to form the basis of any legislation advanced by the committee this year. Senate Republican leaders Mike Crapo (R-ID) and Richard Burr (R-NC) also [reintroduced](#) their counterproposal last week, known as the Lower Costs, More Cures Act.

The Wyden proposal: The principles focus on granting the government the authority to negotiate prices for certain drugs, reducing patient out-of-pocket costs, applying inflation rebates, extending price reforms to the commercial market and ensuring the patent system rewards innovation. These principles are intentionally broad as key details -- such as recommended specifications for Part D redesign -- are still being negotiated. Specifically, the five principles include:

- Medicare must have the authority to negotiate with pharmaceutical companies, especially when competition and market practices are not keeping prices in check.

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- American consumers must pay less at the pharmacy counter.
- Prices of drugs that increase faster than inflation will not be subsidized by patients and taxpayers.
- Drug pricing reforms that keep prices and patient costs in check should extend beyond Medicare to all Americans, including those covered by employer and commercial health plans.
- Drug pricing should reward scientific innovation, not gaming of the patent system.

Sen. Wyden’s principles largely align with major provisions of House Democrats’ bill ([H.R. 3](#)) with the notable omission of any reference to international prices in negotiation. The references to prescription drug “market failures” also suggest that Sen. Wyden intends for negotiation to be more targeted than proposed in H.R. 3, which would permit government price negotiation of up to 250 drugs. The principles also specifically note that the rebate rule, finalized last November and delayed until Jan. 1, 2023, which removes safe harbor protections for price reductions (e.g., rebates) offered by drug manufacturers to pharmacy benefit managers (PBMs) and Part D plans, should be blocked.

- Enhanced Eligibility for Medical Assistance Benefits for Workers and Disabilities (MAWD) Program Awaits Governor’s Signature
- General Assembly Passes State Budget for FY2021-2022

GOP Approach: Mirroring legislation released by House Republicans, Sen. Crapo’s and Sen. Burr’s legislation aims to:

- Modernize payments for drugs delivered in the doctor’s office under Medicare Part B
- Incentivize lower-cost alternatives, or biosimilars
- Establish an annual out-of-pocket cap of \$3,100 for Medicare Part D enrollees and allow certain patients to pay in monthly installments
- Decrease beneficiary cost-sharing from 25 percent to 15 percent of costs before the out-of-pocket cap is reached
- Allow prescription drug plan sponsors to offer, at minimum, up to four Part D plans per region, spurring competition and innovation
- Make permanent the Center for Medicare and Medicaid Innovation model that enables Part D enrollees taking insulin to limit out-of-pocket costs to \$35
- Allow state Medicaid programs to enter in outcomes-based agreements to pay for life-saving gene therapy treatments

- Provide the HHS Secretary with the authority to require drug manufacturers to provide pricing information on all direct-to-consumer advertising
- Codify a Trump Administration regulatory action that classifies insulin and other treatments for chronic conditions as preventative care so that high deductible health plans can cover costs before the patient reaches the deductible
- Create a trade negotiator solely dedicated to putting American patients first in government trade negotiations related to medicines in order to prevent foreign free-loading off America's investment

Highmark joins [AHIP](#), [BCBSA](#) and the [AHA](#) in working with the [Campaign for Sustainable Rx Pricing](#) (CSRxP), to promote bipartisan, market-based solutions to lower drug prices. The CSRxP issued a [statement](#) on the release of drug pricing principles saying “The momentum for Congress to hold Big Pharma accountable and deliver relief for millions of Americans struggling to afford their medications has never been greater.”

House Committee Holds Hearing on SDOH, MLR and Maternal Health Bills

On Thursday, the House Energy and Commerce Subcommittee on Health held a [hearing](#) to discuss 12 bills, including legislation on social determinants of health (SDOH) and proposals to address Black maternal health.

During the hearing, lawmakers considered several bills, including two Black maternal health “M omnibus” proposals — the [Data to Save Moms Act](#) and the [Social Determinants for Moms Act](#). In addition, committee members discussed the [Social Determinants Accelerator Act](#), which would provide \$25 million in planning grants and technical assistance to state, local and Tribal governments to help them devise innovative, evidence-based approaches to coordinate services and improve outcomes and cost-effectiveness. Also included in the discussion was [H.R. 3969](#), which would amend title XXVII of the Public Health Service Act to include activities to address social determinants of health in MLR calculations.

A full list of bills considered is available [here](#).

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Administration Seeks Input on New Drug Price Reporting Requirement

A group of federal agencies is seeking [comment from stakeholders](#) around implementation of a new statutory requirement under the Consolidated Appropriations Act, 2021, regarding drug price reporting to the federal government. The reporting requirements will directly apply to group health plans and health insurance issuers in the individual and group markets, while the Office of Personnel Management is seeking input on whether to extend to carriers participating in the Federal Employees Health Benefits program covering almost 9 million federal employees and dependents.

The RFI specifically requests comments on the data elements and method and manner of reporting, including required various reporting of the 50 most frequently dispensed brand prescription drugs and the top 50 prescription drugs with the greatest increase in plan expenditures. Plans and issuers must also report rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, including the amount paid with respect to each therapeutic class of

drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year.

Comments to the RFI are due July 23, 2021, and should be followed by rulemaking, with the first report required by the statute by December 27, 2021. Data must be publicly available by June 2022.

CMS Announces \$20 Million to Improve Access to State-based Marketplace Coverage

The Centers for Medicare & Medicaid Services (CMS) [announced](#) \$20 million in American Rescue Plan funding to support State-based Marketplaces to improve access to affordable, comprehensive health insurance coverage for consumers in their states. States can apply for funding to help modernize or update their systems, programs, or technology to comply with federal Marketplace requirements, including the recent provisions of the American Rescue Plan that increased the financial assistance available to certain consumers.

Why this matters: State-based Marketplaces can prioritize funding to make modifications to systems or technology infrastructure related to the implementation of applicable federal requirements. States may also use the funds for program policies or procedures required for implementation of applicable federal requirements. Applications will be due July 20 and CMS anticipates issuing grant awards in early September 2021.

CMS Revokes Medicaid Work Requirements in Indiana and Arizona

Centers for Medicare & Medicaid Services (CMS) Administrator Chiquita Brooks-LaSure sent letters to [Indiana](#) and [Arizona](#) officials formally revoking permission for their states to mandate certain low-income adults work, volunteer, or attend school in order to get Medicaid coverage. The letters stated the work requirements in Arizona and Indiana “are not likely to promote the objectives of the Medicaid statute.”

The Biden administration began the process of withdrawing approval for Medicaid work rules in February, sending letters to the 13 states who gained approval during the prior administration. The letters stated the administration’s intention to review all approvals to determine whether they satisfy the requirements of a 1115 waiver being “likely to assist in promoting the objectives” of Medicaid. The administration has since revoked 6 states’ waivers, but still hasn’t made a decision on work rules in several states such as Georgia, Ohio, South Carolina and Utah.

Georgia [sent a letter](#) to CMS notifying the agency it would be delaying its planned July 1 start of its partial Medicaid expansion program which includes work requirements to provide the state with more time to negotiate its 1115 waiver with the administration.

COVID-19 Updates

- The Advisory Council on Immunization Practices (ACIP) held its June meeting last week. The first day specifically focused on the COVID-19 vaccine. Members discussed incidences of myocarditis and pericarditis associated with the use of mRNA COVID-19 vaccines in adolescents and young adults. The group assessed the risk-benefits associated with the mRNA vaccines, updating clinical considerations for incidences of myocarditis/pericarditis, and stressed the need for additional

information to be added to the FDA fact sheet and CDC guidance warning of potential side effects. The FDA has since noted they are preparing to “quickly” add the warning to the mRNA vaccines’ fact sheets after the panel’s discussion. Members also asked CDC staff to continue long term follow-up studies and emphasized the need for data on race and ethnicity. The committee also discussed a potential COVID-19 booster vaccine, stating that more data is needed to determine its necessity and safety before any recommendations can be made.

- The Biden Administration announced the U.S. had administered 300 million COVID-19 vaccines in just 150 days. To date, approximately sixty-five percent of American adults have received at least one shot, including eighty-seven percent of seniors.

State Issues

New York

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COVID-19 State of Emergency Expires

After almost 15 months of operating under Executive Orders, last week Governor Cuomo announced that he would be letting the COVID-19 State of Emergency expire at midnight on June 24. On June 25 the Governor signed Executive Order 210, which rescinds Executive Orders 202 and all subsequent orders through 202.111 and Executive Order 205 – 205.3, which together contain a multitude of COVID related directives and statutory waivers. Accordingly, all of the statutory flexibility that had been granted through executive order and any remaining “active” industry guidance issued by the Department of Health is suspended. The Governor has, however, reiterated that current CDC guidance, which, among other things, requires unvaccinated people to wear masks and social distance, still remains in effect. These rules apply to all people riding public transportation and also applies to those in health care settings, nursing homes, correctional facilities, and homeless shelters, and would be enforced by State and local departments of health.

State Issues

Pennsylvania

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Senate Committee Advances Prior Authorization and Telemedicine Legislation

On Wednesday, June 23, the Senate Banking and Insurance Committee advanced the following bills:

[Senate Bill 225](#) (Phillips-Hill, R-York). Senate Bill 225 would limit health insurer’s ability to operate efficient utilization management processes. Senate Bill 225 would also provide for step therapy protocols and would

require insurers to make available an electronic communications network that permits prior authorization requests to be submitted electronically.

[Senate Bill 705](#) (Vogel, R-Beaver). Senate Bill 705 would define telemedicine services, offer guidelines outlining who can provide telemedicine services, and establish requirements on health insurance company reimbursement for telemedicine services.

Enhanced Eligibility for Medical Assistance Benefits for Workers with Disabilities (MAWD) Program Awaits Governor's Signature

On Friday, June 25, the House unanimously passed [Senate Bill 156](#) (Mensch, R-Berks) which would create a new category under the Medical Assistance Benefits for Workers with Disabilities (MAWD) program termed “worker with job success” and would increase the income eligibility limit from \$32,000 to \$76,000 annually so more individuals are eligible for the MAWD program. A “worker with job success” designation would pay 7.5% of their monthly income to the Department of Human Services as a premium for their medical assistance benefits. Senate Bill 156 has passed unanimously in both chambers and now awaits the governor's signature.

Why this matters: Senate Bill 156 would allow individuals with disabilities the opportunity to work to their full potential without the fear of losing health care benefits due to income limits.

General Assembly Passes State Budget for FY2021-2022

On Friday, June 25, the General Assembly passed a \$40.8 billion state budget for FY 2021-2022. The plan offers increases in funding to education and human services with no tax or fee increases. \$2 billion in surpluses from FY 2020-2021 were placed in the state Rainy Day Fund. Pennsylvania received \$7.3 billion in federal aid from the American Rescue Plan, with \$1 billion being used toward the FY 2021-2022 budget. \$5 billion in unspent American Rescue Plan dollars will be used to fund future state budgets. Approximately two-thirds of increased new spending in the FY 2021-2022 budget is directed to human services, including Medicaid. The governor has indicated that he will sign the FY 2021-2022 budget, as the new fiscal year begins July 1.

The Pennsylvania House of Representatives and the Pennsylvania Senate have adjourned. They will reconvene Monday, September 27.

The Delaware Legislature is in session June 29-30.

The New York Legislature concluded session on June 10.

The West Virginia Legislature concluded session on April 10.

Congress

The U.S. House is in session June 28-July 1. The U.S. Senate is in recess.

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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