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Health Policy Update – June 29, 2021

Senate Finance Chair Releases Drug Pricing Principles as Republican Lawmakers Re-Introduce Lower Costs, More Cures Act

On June 22, Senate Finance Committee Chairman Ron Wyden (D-OR), unveiled a set of principles for drug pricing reform. The principles document calls for:

1. Equipping Medicare with the authority to negotiate with pharmaceutical companies, especially when competition and market practices are not keeping prices in check,
2. Ensuring Americans pay less in out-of-pocket costs,
3. Requiring rebates for drugs whose prices increase faster than inflation,
4. Extending drug pricing reforms to all Americans, not just Medicare beneficiaries; and
5. Rewarding scientific innovation through the continued support of federal R&D funding for groundbreaking treatments while cracking down on companies that attempt to game the patent system.

While the document highlights the chairman's priorities, it contains few details, demonstrating the challenge Wyden faces in finding consensus on this issue. For example, unlike H.R. 3, the drug pricing bill introduced by House Democrats that calls for Medicare to cap drug prices at 120% of the average price in six comparator countries and institutes tax penalties on drug makers who don't comply, Wyden's principles simply state that Congress should give the Secretary the tools and guidance to negotiate a fair price and create the right incentives to ensure drug maker participation. Wyden notes that legislation will continue to be developed with input from members on and off the committee.

That same day, Senators Mike Crapo (R-ID), Ranking Member of the Senate Finance Committee, and Richard Burr (R-NC), Ranking Member of the Senate HELP Committee, reintroduced the Lower Costs, More Cures Act (S. 2164). Among other provisions, the bill would create a tiered system for Part B drug reimbursement, create a maximum add-on payment of up to $1,000 for most drugs and biologics ($2,000 for immunotherapies), implement site neutral payments for the services associated with administering a Part B drug, and redesign the Medicare Part D benefit.

To read the drug pricing reform principles released by Chairman Wyden, CLICK HERE.

To read the Senate Finance Committee release about the Lower Costs, More Cures Act, CLICK HERE.

Lawmakers Unveil Bipartisan Cures 2.0 Legislation

On June 22, U.S. Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) released a draft of the highly anticipated Cures 2.0 bill, bipartisan legislation designed to build upon the 21st Century Cures Act, which was signed into law in 2016 and modernized the way the United States develops new cures and treatments for conditions such as cancer, Alzheimer's, diabetes, and infectious diseases. The legislation release coincides with a detailed concept paper the White House published Tuesday in Science Magazine outlining the Administration's vision for the Advanced Research Projects Agency for Health (ARPA-H), the proposed research agency to be housed within the National Institutes for Health.

The Cures 2.0 bill includes the ARPA-H proposal, which would authorize at least $6.5 billion to set up the new agency, whose stated mission is to "make pivotal investments in breakthrough technologies and broadly applicable platforms, capabilities, resources, and solutions that have the potential to transform important areas of medicine and health for the benefit of all patients and that cannot readily be accomplished through traditional research or commercial activity."

The draft legislation also includes a number of proposed reforms, including a provision to permanently eliminate Medicare's site-of-service and geographic limitation requirements that were temporarily waived in response to the COVID-19 pandemic. FDA-related provisions would incentivize better clinical trial designs, increase the use of real-world and patient experience data, and establish a regulatory framework for gene therapies and new digital health technologies. In addition, the draft bill codifies an existing rule that would provide Medicare coverage for FDA-designated breakthrough devices and establishes a new reimbursement framework for manufacturers that develop new antibiotics.

The Cures 2.0 bill is expected to be formally introduced in the House of Representatives in the coming weeks.

To read a discussion draft of the legislation, CLICK HERE.

To read a section-by-section summary of the bill, CLICK HERE.

To read the White House's concept paper in Science Magazine, CLICK HERE.

To read a fact sheet about ARPA-H, CLICK HERE.

Affordable Care Act Survives Third Supreme Court Challenge

On June 17, the Supreme Court ruled 7-2 to dismiss a case challenging the constitutionality of the Affordable Care Act. The suit, filed by a coalition of Republican-led states, sought to determine whether a 2017 decision by Congress to remove the tax penalty for not having health insurance rendered the entire law unconstitutional. Writing for the majority, Justice Stephen Breyer's argued that states and individual plaintiffs do not have legal standing to challenge the law because the plaintiffs are not harmed by not having to pay the tax penalty.

Democrats celebrated the decision, with some lawmakers now urging Congress to further build on

the ACA by expanding federal subsidies, closing the “Medicaid gap” in states that haven’t expanded the program, lowering prescription drug costs, and adding additional covered services to Medicare. President Biden has also signaled that now is the time to bolster the ACA and said he looks forward to working on it with Congress.

The ruling has also received praise from the biosimilar drug development industry. Biosimilars offer a lower-cost alternative to name-brand biologics and striking down the ACA would have undone the federal framework for reviewing and approving biosimilars. The Biologics Price Competition and Innovation Act, which establishes that framework, was enacted via a provision of the ACA.

The Cures 2.0 bill is expected to be formally introduced in the House of Representatives in the coming weeks.

To read the Supreme Court’s majority opinion, CLICK HERE.

Bipartisan Pharmacy DIR Reform Introduced in Congress

A bipartisan group of lawmakers in both houses of Congress recently introduced legislation to reform pharmacy direct and indirect remuneration (DIR) fees. The Pharmacy DIR Reform to Reduce Senior Drug Costs Act (H.R. 3554/S.1909) aims to ensure that pharmacy price concessions are assessed at the point of sale and to hold Pharmacy Benefit Managers (PBMs) accountable for retroactively assessing fees on pharmacies.

DIR fees are charged to pharmacies by Part D plans or their PBMs after a drug is dispensed to reflect changes that may have affected the final cost of a drug. They can also be used to assess a pharmacy’s performance. In recent years, PBMs have increasingly returned to pharmacies days or even weeks after the point-of-sale to demand additional DIR fees, putting considerable strain on pharmacy finances. According to the bill’s sponsor, from 2010 to 2019, CMS documented a 91,500 percent increase in DIR fees paid by pharmacies. The new bill aims to reverse this trend by:

- Redefining "negotiated price" under statute to include all pharmacy price concessions at the point-of-sale so that a senior's cost-sharing will reflect all possible discounts.
- Eliminating the retroactive nature of DIR clawback fees.
- Improving transparency in price concessions and fees by requiring prescription drug plans and Medicare Advantage drug plans to report any pharmacy price concession or incentive payment they apply after the point-of-sale to a pharmacy on at least an annual basis.
- Establish a new pharmacy performance evaluation system to ensure that the measures a prescription drug plan or Medicare Advantage drug plan uses to assess pharmacy performance are fair, reliable, consistent, and transparent.

To view the legislation, CLICK HERE.

To read the press release on the bill from lead Democratic sponsor, Senator Jon Tester (D-MT), CLICK HERE.

To read a statement in support of the bill from the National Community Pharmacists Association, CLICK HERE.

HHS Rescinds 340B Advisory Opinion After Court Declines to Dismiss Lawsuit Challenging Agency's Authority

On June 18, HHS revoked a previous advisory opinion that stated drug makers must provide products discounted under the 340B program to contract pharmacies after a federal court in Delaware allowed a lawsuit brought against the policy by AstraZeneca to move forward.

The Department first issued the opinion in December 2020 after a dispute between hospitals and drug manufacturers over whether the manufacturers could refuse to provide discounted drugs through contract pharmacies. Drug makers alleged the hospitals were claiming "double discounts" this way. After HHS appeared to side with the hospital industry in this dispute when it issued the advisory opinion, several drug manufacturers, including AstraZeneca, sued.

HHS' stated justification for withdrawing advisory opinion is to "avoid confusion and unnecessary litigation" and claimed in a recent court filing that the lawsuit is now moot. However, the department still plans to enforce existing rules which include fining drug manufacturers who fail to provide discounts through contract pharmacies claiming the advisory opinion was unnecessary for continued enforcement.

To view HHS' most recent federal court filing, CLICK HERE.

To view the now-withdrawn advisory opinion, CLICK HERE.

MedPAC Recommends Streamlining CMMI Models

In its June 2021 report to Congress, the Medicare Payment Advisory Commission (MedPAC) recommended program changes to streamline and scale back the number of alternative payment models administered by the Centers for Medicare and Medicaid Innovation (CMMI) while overhauling the current system of Medicare Advantage (MA) payments.

Concerning CMMI models, MedPAC suggested the agency focus on a smaller and more targeted suite of models that are designed to be temporary and limited in scope. In its report, the Commission noted that many of these models appeared to generate savings for the Medicare program but overlapping participation among providers and patient pools makes it hard to measure the true savings. To accomplish this, MedPAC said CMMI could consider focusing on a single population-based model with different tracks by provider type or beneficiary population, or limit models to particular geographic areas of the country. To minimize complexity, MedPAC suggested that the payment models in CMS's portfolio could use consistent model parameters (e.g., consistent methods for calculating spending targets and measuring quality). The Commission predicted a

smaller, more harmonized portfolio of models would make financial incentives more predictable and reduce providers' administrative burden, as well as lead to other payers adopting models with common features.

To view MedPAC's June 2021 report, CLICK HERE.