
Health Policy Update – March 16, 2018

House Fails to Pass Right to Try Legislation

On March 13, the House of Representatives failed to advance a bill to allow patients easier access to experimental treatments that have not yet received FDA approval. The measure garnered a 259-140 majority vote that fell short of the two-thirds majority required for passage under expedited consideration. While the Senate unanimously approved a similar bill, the House version attracted significant opposition from House Democrats and health experts who feared the bill could compromise patient safety.

According to a fact sheet from the House Energy & Commerce Committee, the House “Right to Try” legislation would:

- Specify that any unapproved drug used in the new alternative pathway must have an active application and is not the subject of a clinical hold;
- Include a sponsor and manufacturer notification to the FDA after they make an unapproved drug available to an eligible patient;
- Guard patients from manufacturers purposefully misbranding or mislabeling drugs;
- Provide liability protections for manufacturers, sponsors, physicians, clinical investigators, and hospitals that participate in the existing expanded access program and the new alternative pathway; unless there is reckless or willful misconduct, gross negligence, or an intentional tort;
- Obligate sponsors and manufacturers to report adverse events in real time, through notification to the FDA – both within the existing expanded access program and through the new alternative pathway; and
- Provide certainty to manufacturers regarding how the FDA will use patient outcomes when evaluating new drug applications.

Despite the set-back, the House could pass a similar measure under regular order. Republican leadership could alternatively negotiate with their Democratic counterparts to include some or all of the bill’s provisions into the omnibus spending measure expected later this week.

To view the House Right to Try legislation, [CLICK HERE](#).

To view the House E&C fact sheet [CLICK HERE](#).

Senate HELP Committee Hearing Examines 340B Program

On March 15, the Senate Committee on Health, Education, Labor & Pensions (HELP) hosted a hearing, “Perspectives on the 340B Drug Pricing Program,” marking the first time the Committee has ever held a hearing dedicated solely to the 340B program.

Several Senators had questions about potential reforms to the program including increased transparency in how hospitals are using 340B savings and whether the 340B drug discount is being passed directly to patients. Other Senators questioned witnesses about the need for transparency from drug manufacturers and issues related to drug pricing. Chairman Lamar Alexander (R-TN) indicated the Committee would hold another hearing on the topic later this year.

The 340B drug discount program has been criticized for allowing many hospitals to take advantage of cheaper drugs without having to demonstrate how the resulting savings are used to provide better patient care. Last year, the Centers for Medicare & Medicaid Services (CMS) announced it would be cutting Part B drug payments under the 340B by \$1.6 billion and reallocating the savings to increase reimbursements for other non-drug items and services.

A coalition of hospital groups led by American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals filed a lawsuit against CMS to stop the cuts, however the suit was rejected by a federal judge and is currently awaiting an appeal.

Witnesses at the hearing included:

- [Bruce Siegel](#), MD, MPH, President and Chief Executive Officer, America's Essential Hospitals
- [Lori M. Reilly](#), Executive Vice President, Pharmaceutical Research and Manufacturers of America
- [Sue Veer](#), MBA, President and Chief Executive Officer, Carolina Health Centers, Inc.
- [Joseph M. Hill III](#), MA, Director, Government Relations Division, American Society of Health-System Pharmacists

To view the HELP Committee hearing, [CLICK HERE](#).

House, Senate Committees to Hold Hearings on Opioid Crisis

Later this month, the House Energy & Commerce Subcommittee on Health will hold a [two-day legislative hearing](#) on March 21 and 22 to consider 25 bills related to the opioid crisis. Bills under consideration at the hearing will include:

- The INFO Act ([H.R. 4284](#)) to streamline efforts within health organizations for grants and other funding related to opioids
- Jessie's Law ([H.R. 5009](#)) to require the Department of Health and Human Services to develop standards for hospitals and physicians to show a patient's history of opioid addiction when receiving treatment
- The ACE Research Act ([H.R. 5002](#)) to expand research efforts into opioids for the National Institutes of Health
- The Overdose Prevention and Patient Safety Act ([H.R. 3545](#)) to permit substance use disorder (SUD) records to be shared without patient consent, in accordance with Health Insurance Portability and Accountability Act (HIPAA)

Separately, the Senate HELP Committee invited Governors Kate Brown (D-OR) and Larry Hogan (R-MD) to testify about their experience fighting the opioid crisis and how the federal government can help. Both Governors agreed that more federal funding was needed to better address the crisis.

To view a full list of the opioid bills under consideration in the House, [CLICK HERE](#).

To view the Senate HELP Committee hearing, [CLICK HERE](#).

FDA Administrator Criticizes PBMs in Recent Remarks

On March 7, FDA Administrator Scott Gottlieb delivered strongly critical remarks about pharmacy benefit managers (PBMs), criticizing the industry's practice of leveling fees on drug list prices after securing considerable rebates from manufacturers in exchange for preferable formulary space. He also accused them of discouraging the development of biosimilar therapies.

"They use their individual market power to effectively split monopoly rents with large manufacturers and other intermediaries; rather than passing on the savings garnered from competition to patients and employers," Dr. Gottlieb stated at the America's Health Insurance Plans (AHIP) annual meeting. "The rigged payment scheme might quite literally scare competition out of the market altogether."

PBMs, the middlemen between insurance plans and drug manufacturers, have been accused of contributing to high drug prices by failing to pass down the savings they negotiate from manufacturers on to patients.

To view a transcript of Gottlieb's remarks to AHIP, [CLICK HERE](#).

HHS Secretary Azar Discusses Value-Based Care, Drug Pricing Transparency

Last week, Health and Human Services (HHS) Secretary Alex Azar delivered remarks outlining the Administration's goals for controlling healthcare costs while expanding competition and choice among healthcare consumers and promoting value-based care. In his speech, which was delivered at a Federation of American Hospitals conference on March 5, Azar called for a transition to a value-based system of care where payment for healthcare services is based on the ability to provide meaningful benefits to patients.

Azar also weighed in on United Healthcare's recent changes to its drug discount program, calling it a positive step towards transparency that will help lower out-of-pocket drug costs for patients. In early March, [United Healthcare announced](#) that it will begin passing drug manufacturer rebates to consumers at the point of sale instead of using those savings to lower premiums.

Azar also criticized PBMs, remarking that the way drug discounts are currently arranged "too often generates profits for middlemen rather than savings for patients."

To view Secretary Azar's remarks, [CLICK HERE](#).

CMS Rejects Idaho's Plan to Sell Non-ACA Compliant Insurance Plans

On March 9, the Centers for Medicare & Medicaid Services (CMS) rejected a proposal by Idaho to allow insurers to sell health plans that don't comply with the Affordable Care Act's requirements.

CMS did however send state officials a letter encouraging Idaho officials to modify their regulations and allow insurers to offer "short term" policies. In February, the Administration issued a proposed rule expanding the use of short-term health plans. Insurers would now be able to sell short-term plans – which do not need to comply with the ACA's regulations including the ban on discrimination for a pre-existing condition - for nearly a year up from the current three months.

Critics of the Idaho proposal argue that expanding the availability of non-ACA compliant plans would put a strain on the individual insurance market. If enough young, healthy consumers opt for the cheaper plans the remaining pool would be left with older, sicker and higher-cost patients who would face higher premiums.

To read CMS' letter to Idaho Governor C.L. "Butch" Otter and Idaho Insurance Director Dean Cameron, [CLICK HERE](#).