



Health Policy Briefing

October 14, 2019

Congressional Budget Office Releases Partial Score of Speaker Pelosi’s Signature Drug Pricing Legislation

On Friday, the Congressional Budget Office (CBO) released a [preliminary estimate](#) of the effects of Title I of H.R. 3, the *Lower Drug Costs Now Act of 2019*, which is Speaker Pelosi’s signature drug pricing reform bill. Title I requires drug manufacturers to negotiate prices with the Secretary of Health and Human Services (HHS), subject to a cap of 120% of the average price in six other countries. CBO estimates that Title I would result in Medicare savings of \$345 billion between 2023 and 2029. CBO further notes that foreign drug prices are expected to rise and that the steep cuts to manufacturer revenues would result in “lower spending on research and development and thus reduce the introduction of new drugs.” Reactions from lawmakers were swift. Energy and Commerce Committee Chairman Pallone (D-N.J.), Ways and Means Committee Chairman Neal (D-Mass.), and Education and Labor Chairman Scott (D-Va.) jointly stated that the CBO analysis confirms that “H.R. 3 lives up to its name of lowering prescription drug costs for the American people.” On the other side of the aisle, Energy & Commerce Committee Ranking Member Walden (R-Ore.) stated that Speaker Pelosi is “jamming through her drug pricing scheme, moving forward with less than a full picture to tip the scale, and trick the public.” Meanwhile, Ways and Means Committee Ranking Member Brady (R-Texas) stated that, “CBO’s report confirms House Democrats’ ‘dictate or destroy’ price controls only serve to hurt the development of future cures and damage American innovation.” Democrats remain committed to advancing the legislation, with the Ways and Means Committee scheduled for a [hearing](#) on the topic this Thursday. Additionally, House Majority Leader Hoyer (D-Md.) wrote in a letter to colleagues that it is “possible” the House will vote on the measure during the week of October 28.

Inside

- [Pending Drug Importation Guidance.....](#)2
- [HHS Releases Long-Awaited Rules Reforming Stark & Antikickback Statute Regulations.....](#)2
- [House Continues Work to Address Surprise Billing.....](#)3
- [Trump Signs Two Executive Orders Intended to Reign in Federal Bureaucracy.....](#)3
- [Members of Congress Ask Attorney General to Review Purdue Pharma’s Proposed Bonuses.....](#)3
- [Medicaid Enrollment Drops.....](#)4
- [Representative Nita Lowey to Retire.....](#)4
- [CDC Issues Revised Vaping Guidance.....](#)4
- [Upcoming Congressional Hearings and Markups.....](#)4
- [Recently Introduced Health Legislation.....](#)5

Pending Drug Importation Guidance

Last Monday, a draft guidance related to prescription drug importation landed at the Office of Management and Budget (OMB) for [review](#). The guidance follows the Administration's "[Safe Importation Plan](#)" to create two pathways to import drugs from abroad. Under Pathway 1, a Notice of Proposed Rulemaking would be released to authorize demonstration projects allowing importation of drugs from Canada. Under Pathway 2, manufacturers could import versions of FDA-approved drugs that they sell in foreign countries that are the same as the U.S. versions of those products. While the exact content of the draft guidance is unknown until OMB concludes its review, it is likely that the guidance focuses on Pathway 2, since it is a "Draft Guidance for Industry," not a proposed regulation or a notice thereof, as contemplated by Pathway 1. Interestingly, the title of the guidance explicitly states that biologics are included in its scope, which has been a sticking point for some stakeholders in the past. The safe importation of large-scale, complex molecules requiring specific storage and handling conditions presents much greater logistical challenges than that of small molecules. It remains to be seen whether the guidance carves out the most complex products. The exact timing of the completion of OMB review is unknown. However, importation remains a priority for this Administration, with the President previously announcing that importation was coming "soon" during remarks in Florida on October 3rd.

HHS Releases Long-Awaited Rules Reforming Stark & Antikickback Statute Regulations

On Wednesday, HHS released two separate rules directed at reforming fraud and abuse regulations to better reflect the administration's goal of moving the health care system toward value-based payment and delivery models. The first, is a [proposed rule](#) from the Centers for Medicare and Medicaid Services (CMS) which seeks to reform the physician self-referral prohibitions (a.k.a. "the Stark law") and the corresponding exceptions that allow some compensation arrangements to avoid running afoul of the law and regulations. CMS has received numerous stakeholder complaints over the years that the Stark rules have inhibited the ability of providers to create and implement value-based payment arrangements and have served as a barrier to moving toward alternative payment models (APMs). The proposed rule includes exceptions for compensation arrangements that qualify as "value-based arrangements." CMS also provides additional guidance as well as a new exception directed at donations of cybersecurity technology. The second, is a [proposed rule](#) from the HHS Office of the Inspector General (OIG) which seeks to make parallel policies that would provide protections for value-based arrangements under the Antikickback Statute (AKS) (and corresponding Civil Monetary Penalties (CMP) statute). The proposed rules also provide a cybersecurity technology donation safe harbor and a provision directed at protecting beneficiary incentives for utilization of telehealth for certain in-home dialysis patients. The rules have yet to be published in the Federal Register, but according to a CMS Fact Sheet, comments will be due by December 31, 2019.

House Continues Work to Address Surprise Billing

As Congress returns from a two-week recess, two key House Committees – Ways and Means and Education and Labor – plan to move forward with their own surprise billing legislation. While neither committee has formally announced a date to markup the critical legislation, Ways and Means Committee Chairman Richard Neal (D-Mass.) sent a [letter](#) to his Democratic committee colleagues proposing negotiated rulemaking to “address the [payment] disagreements” related to surprise medical bills, noting that “[t]his process has already been successfully used in the healthcare context.” Given the initial reaction to the proposal, Chairman Neal reportedly has since indicated that the Committee may opt to move in a different direction.

Members of the Education and Labor Committee are also continuing their work on surprise billing and will likely use the introduced version of H.R. 3630, the ***No Surprises Act***, as the starting point for their deliberations. H.R. 3630 was reported out of the Energy and Commerce Committee in July but was also referred to the Education and Labor Committee for consideration. However, 20 members of the committee are cosponsors of a competing bill, H.R. 3502, the ***Protecting People From Surprise Medical Bills Act***, introduced by Reps. Raul Ruiz (D-Calif.) and Phil Roe (R-Tenn.). While H.R. 3502 includes a comprehensive independent dispute resolution (IDR) process, it was reported that CBO stated in an email that the IDR process as proposed in this bill would cost “double digit billions”. The cost may complicate inclusion in a final bill. While the bill that came out of Energy and Commerce also has an IDR, it is very limited in its scope so the provider community would like to see additional improvements.

On the Senate side, Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-Tenn.) continues to work with Sen. Bill Cassidy (R-LA) on inclusion of an IDR process in the HELP-passed product.

Trump Signs Two Executive Orders Intended to Reign in Federal Bureaucracy

Last Wednesday, President Trump signed two executive orders focused on reining in federal bureaucracy. The first [order](#) noted that “[a]gencies shall act transparently and fairly with respect to all affected parties, as outlined in this order, when engaged in civil administrative enforcement or adjudication,” while the second [one](#) requires public comment on certain guidance documents. In contrast to the Obama administration, which had a focus for broadening the scope of regulatory interpretation to include letters, memos, blogs, and brochures, these two executive orders are intended to reduce the reach of federal agency interpretations. In response to signing the orders, Public Citizen issued a [press release](#) stating that “regulatory guidance has been crucial to protecting the public in countless ways” and noted that the new orders would undermine the FDA’s ability to implement a ban on flavored vaping products.

Members of Congress Ask Attorney General to Review Purdue Pharma’s Proposed Bonuses

On October 7, Representatives Bustos (D-Ill.) and Burchett (R-Tenn.) [wrote](#) to Attorney General William Barr, expressing “deep concern” about reports that Purdue Pharma is seeking court permission to make bonus payments of up to \$38 million to employees in the midst of its bankruptcy proceedings. The two lawmakers have previously introduced the ***No Bonuses in Bankruptcy Act of 2019***, which would prevent companies in bankruptcy proceedings from paying bonuses to certain employees. The letter requests that the Department of Justice seek additional information on the proposed bonus payments, including which employees making more than \$250,000 annually are to receive these bonuses and what the rationale is for providing bonuses at this time. Purdue is in bankruptcy proceedings as a result of extensive litigation alleging that the company improperly marketed its opioid medications, thereby contributing to the national opioid crisis.

Medicaid Enrollment Drops

According to analysis by the Medicaid and CHIP Payment and Access Commission (MACPAC) examining data from May 2017 to May 2019, enrollment in Medicaid and the State Children's Health Insurance Program (CHIP) decreased by 2.5% -- the largest drop over a 2-year period in over forty years. Of the 1.9 million people who fell off the rolls for these programs, many are still eligible for program assistance but are being lost to follow-up and similar program complications, including implementation of new work and income verification requirements. Fewer insured Americans could mean a spike in costs for insured patients and increases in uncompensated hospital care. An analysis of national and state trends for Medicaid and CHIP enrollment was presented and discussed at the MACPAC's [September 26 meeting](#).

Representative Nita Lowey to Retire

On Thursday, Nita Lowey (D-N.Y.) announced that she will not be seeking re-election in 2020. The 82-year-old was first elected to Congress in 1988 and is retiring as the Chair of the powerful House Appropriations Committee; she's the first woman to hold that post. Lowey's health care accomplishments include strong support for biomedical research and the *Affordable Care Act* (ACA); a focus on women's health including authoring the *Breast Cancer and Environmental Research Act* and supporting the WISEWOMAN Program; and being a champion for families including authoring the *Food Allergen Labeling and Consumer Protection Act* which mandated clear, concise food allergen labeling and authoring the *Sunscreen Consumer Right to Know Act* which required the FDA to issue sunscreen standards. Rep. Rosa DeLauro (D-Conn.) announced her intent to run for the chairmanship of the Appropriations Committee in the next Congress. Rep. DeLauro currently chairs the Labor, HHS and Education Subcommittee.

CDC Issues Revised Vaping Guidance

On Friday, the Centers for Disease Control and Prevention (CDC) released updated [interim guidance](#) to help clinicians assess, evaluate, manage, and follow-up with individuals who may have lung illnesses due to vaping. The guidance clarifies that clinicians should ask patients who present with flu-like symptoms about their vaping history, given the overlap in symptoms. The guidance also recommends that clinicians tell patients to stop vaping. This updated guidance replaces guidance issued by CDC in August.

Upcoming Congressional Hearings and Markups

Senate Special Committee on Aging hearing titled "Falls Prevention: National, State, and Local Solutions to Better Support Seniors;" 9:30 a.m., 562 Dirksen Bldg.; October 16

House Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies hearing titled "E-cigarettes: An Emerging Threat to Public Health;" 10:00 a.m., 2358-C Rayburn Bldg.; October 16

House Energy and Commerce Health Subcommittee hearing titled "Legislation to Reverse the Youth Tobacco Epidemic;" 10:30 a.m., 2322 Rayburn Bldg.; October 16

House Committee on Veterans' Affairs Subcommittee on Oversight and Investigations hearing titled "Broken Promises: Assessing VA's Systems for Protecting Veterans from Clinical Harm;" 2:00 p.m., HVC 210; October 16

House Ways and Means Committee hearing titled "Investing in the U.S. Health system by lowering drug prices, reducing out of pocket costs, and improving Medicare benefits;" 10:00 a.m., 1100 Longworth Bldg.; October 17

House Committee on Veterans' Affairs Women's Task Force Roundtable Discussion titled "Trends and Opportunities in Interdisciplinary Research Regarding Women Veterans;" 2:00 p.m., 303 Cannon Bldg.; October 17

Recently Introduced Health Legislation

H.R.4669 — To amend title XVIII of the Social Security Act to provide for intelligent assignment of certain subsidy eligible individuals auto-enrolled under Medicare prescription drug plans and MA-PD plans. Sponsor: Rep. Stevens, Haley M. [D-MI-11]; Cosponsors: (3) Committees: House - Energy and Commerce; Ways and Means

H.R.4667 — To amend the 21st Century Cures Act to reauthorize funding for NIH innovation projects, and for other purposes. Sponsor: Rep. Sherrill, Mikie [D-NJ-11]; Cosponsors: (2) Committees: House - Energy and Commerce

H.R.4666 — To amend title XVIII of the Social Security Act to provide certain low-income territorial residents with automatic eligibility for premium and cost-sharing subsidies under the Medicare program, and for other purposes. Sponsor: Rep. Shalala, Donna E. [D-FL-27]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4665 — To amend title XVIII of the Social Security Act to provide coverage for certain vision items and services under part B of the Medicare program. Sponsor: Rep. Schrier, Kim [D-WA-8]; Cosponsors: (3) Committees: House - Energy and Commerce; Ways and Means

H.R.4663 — To amend title XVIII of the Social Security Act to require drug manufacturers to pay a Medicare part B rebate for certain drugs if the price of such drugs increases faster than inflation. Sponsor: Rep. Porter, Katie [D-CA-45]; Cosponsors: (3) Committees: House - Energy and Commerce; Ways and Means

H.R.4661 — To amend title XVIII of the Social Security Act to provide for the automatic qualification of certain Medicaid beneficiaries for premium and cost-sharing subsidies under part D of the Medicare program, and for other purposes. Sponsor: Rep. Pappas, Chris [D-NH-1]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4655 — To amend title XVIII of the Social Security Act to provide for certain rules regarding the treatment of eligible retirement plans in determining the eligibility of individuals for premium and cost-sharing subsidies under part D of the Medicare program, and for other purposes. Sponsor: Rep. Lee, Susie [D-NV-3]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4652 — To establish an Individual Market Reinsurance fund to provide funding for State individual market stabilization reinsurance programs. Sponsor: Rep. Langevin, James R. [D-RI-2]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4651 — To amend the Internal Revenue Code of 1986 to expand health savings accounts, and for other purposes. Sponsor: Rep. King, Steve [R-IA-4]; Cosponsors: (0) Committees: House - Ways and Means

H.R.4650 — To amend title XVIII of the Social Security Act to provide coverage for certain dental items and services under part B of the Medicare program. Sponsor: Rep. Kelly, Robin L. [D-IL-2]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4649 — To amend title XVIII of the Social Security Act to provide for a cap on beneficiary liability under part D of the Medicare program, and for other purposes. Sponsor: Rep. Horsford, Steven [D-NV-4]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4640 — To require persons who undertake Federally funded research and development of drugs to enter into reasonable pricing agreements with the Secretary of Health and Human Services. Sponsor: Rep. DeFazio, Peter A. [D-OR-4]; Cosponsors: (0) Committees: House - Energy and Commerce

H.R.4633 — To amend the 21st Century Cures Act to reauthorize funding for FDA innovation projects, and for other purposes. Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Cosponsors: (1) Committees: House - Energy and Commerce

H.R.4632 — To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to disseminate to part D subsidy eligible individuals information comparing the premiums under LIS benchmark plans for such individuals. Sponsor: Rep. Kind, Ron [D-WI-3]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4631 — To amend the Internal Revenue Code to impose an excise tax on opioid manufacturers, to make the funds collected through such tax available for opioid (including heroin) abuse prevention and treatment programs, and for other purposes. Sponsor: Rep. Rose, Max [D-NY-11]; Cosponsors: (4) Committees: House - Ways and Means; Energy and Commerce; Budget

H.R.4629 — Star Rating for Biosimilars Act Sponsor: Rep. Tonko, Paul [D-NY-20]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.R.4628 — To amend title XVIII of the Social Security Act to eliminate the resource requirement with respect to subsidy eligible individuals under part D of the Medicare program. Sponsor: Rep. Scanlon, Mary Gay [D-PA-5]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4624 — Ending Nicotine Dependence from Electronic Nicotine Delivery Systems Act of 2019 Sponsor: Rep. Krishnamoorthi, Raja [D-IL-8]; Cosponsors: (0) Committees: House - Energy and Commerce

H.R.4622 — Family Asthma Act Sponsor: Rep. Cummings, Elijah E. [D-MD-7]; Cosponsors: (3) Committees: House - Energy and Commerce

H.R.4621 — To require the Secretary of Health and Human Services to issue and disseminate guidance to States to clarify strategies to address social determinants of health under the Medicaid program and the Children's Health Insurance Program, and for other purposes. Sponsor: Rep. Blunt Rochester, Lisa [D-DE-At Large]; Cosponsors: (1) Committees: House - Energy and Commerce

H.R.4620 — More Help for Seniors Act of 2019 Sponsor: Rep. Rose, Max [D-NY-11]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4619 — Pharmaceutical Rebates for Excessive Pricing Above Inflation Act Sponsor: Rep. Schakowsky, Janice D. [D-IL-9]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

H.R.4618 — Medicare Hearing Act of 2019 Sponsor: Rep. McBath, Lucy [D-GA-6]; Cosponsors: (1) Committees: House - Energy and Commerce; Ways and Means

H.Res.622 — Expressing support for designation of the week of October 6, 2019, through October 12, 2019, as "Latex Allergy Awareness Week". Sponsor: Rep. Engel, Eliot L. [D-NY-16]; Cosponsors: (0) Committees: House - Oversight and Reform

H.R.4613 — VA Reporting Transparency Act Sponsor: Rep. Rose, Max [D-NY-11]; Cosponsors: (1) Committees: House - Veterans' Affairs

H.R.4597 — To amend title XVIII of the Social Security Act to eliminate cost sharing for biosimilar biological products furnished under part B of the Medicare program. Sponsor: Rep. Peters, Scott H. [D-CA-52]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means

*H.R.4588 — Modernizing VA's Records Management Program Act Sponsor: Rep. Cox, TJ [D-CA-21]; Cosponsors: (5)
Committees: House - Veterans' Affairs*

*H.R.4585 — Campaign to Prevent Suicide Act Sponsor: Rep. Beyer, Donald S., Jr. [D-VA-8]; Cosponsors: (1)
Committees: House - Energy and Commerce*

*H.R.4583 — Medicare Extra Rx Higher Eligibility Limits in Part D Act of 2019 Sponsor: Rep. Schneider, Bradley Scott
[D-IL-10]; Cosponsors: (2) Committees: House - Energy and Commerce; Ways and Means*