Drug Pricing: What Happened In 2019, What To Watch In 2020

By **Tom Bulleit and Scott Falin** (January 14, 2020)

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Have you heard that drug prices are too high? If not, you have not been listening to President Donald Trump, Secretary of Health and Human Services Alex Azar, or almost any member of Congress. In the past year, a dizzying array of drug pricing actions and proposals have come out of the White House and Congress, as well as the governor's offices and legislative halls in most states.

Despite the unprecedented attention, drug makers increased prices an average of 5.1% to start 2020, compared to average increases of 5.2% in January 2019 and 8.0% in January 2018.[1] While the Trump administration likely will claim that its policies deserve credit for this modest reduction in the rate of increase, there appear to be no signs of any price decreases.

Moreover, apart from a doomed provision for direct government negotiation of prices in House Speaker Nancy Pelosi's bill, and, (perhaps) a not-yet proposed rule for international reference pricing for Medicare Part B, there are not even any current proposals to limit the prices of new drugs. Indeed, this year saw the largest list price for a new drug in American history: $2.1 million for the gene therapy Zolgensma.[2] Drug makers' arguments — that the ability to set their own prices is essential to continue the notable medical triumphs that have resulted from their research and development efforts in the past half century — largely have continued to carry the day.

That said, in the 20 months since the president unveiled his American Patients First campaign (referred to as the blueprint) in May 2018,[3] there has been a great deal of governmental activity that is affecting, and will continue to affect, the ways in which Americans access prescription drugs.

These include reforms of Medicare's prescription drug benefit programs, greater transparency into drug prices and price increases, more support for generics and biosimilars, and the prospect of importing cheaper drugs from other countries. At the same time, just the continuing conversation about (and therefore potential for) more consequential governmental measures — direct negotiation, restructuring the supply chain to channel rebates to consumers instead of middlemen like pharmacy benefit managers, or PBMs, or international reference pricing — is likely to impact, at least at the margins, the behaviors of drug makers, insurers, providers and others.

With this context in mind, this article will recap what happened on prescription drug pricing at the federal and state levels in 2019, and will speculate as to what bears watching in 2020.

The Trump Administration

The Trump administration's drug pricing efforts began in earnest with the May 2018 announcement of the blueprint, which laid out four priorities for curbing prescription drug prices:

- Improve competition;
- Create a framework for better negotiations with drug makers;
- Provide incentives to lower list prices; and
- Reduce patients' out-of-pocket costs.[4]

For each priority, the blueprint provided a laundry list of potential policies. Although many of the proposals would require congressional action which, as discussed below, has been largely lacking thus far, a significant number can be accomplished administratively. Over the past year and a half, the administration has implemented some of those ideas, while abandoning others.

Implemented Policies

Medicare Utilization Controls

The administration has sought to strengthen the negotiating power of private plans that provide coverage to Medicare beneficiaries through Parts C (also known as Medicare Advantage) and D. For example, the Centers for Medicare & Medicaid Services granted Medicare Advantage plans the authority to use step therapy for Part B drugs (i.e., pharmaceutical products traditionally covered under the Part B benefit, such as physician-administered drugs).[5] Step therapy refers to the insurance practice of requiring that a patient try a preferred drug before covering a non-preferred and generally more expensive drug.

CMS also has encouraged Part D plans to use prior authorization and step therapy for protected class drugs. By statute, Part D plans must cover all available drugs in the six protected classes with few exceptions.[6] In a May 2019 final rule, the agency codified its guidance allowing Part D plans to use prior authorization and step therapy for new starts of protected class drugs, except for drugs belonging to the anti-retroviral class.[7]

While such utilization controls improve the ability of Part D plans to steer patients to lower-cost drugs, the impact of such policies will be limited so long as plans must cover all drugs in the protected classes. As discussed below, the administration considered, but ultimately abandoned, a proposal to weaken the protected classes' coverage mandate.

Transparency Initiatives

To incentivize manufacturers to lower list prices, the administration frequently has sought to increase price transparency. Proponents hope that such measures will steer consumers to cheaper alternatives and shame companies into reducing prices to avoid negative publicity.

Transparency initiatives are popular politically because they impose minimal costs on industry and government and do not restrict access to drugs for patients and providers. However, many observers are skeptical that transparency alone will have a significant influence on how manufacturers price their products.[8]

Transparency initiatives implemented or proposed by the Trump administration include:

- New laws prohibiting plans and PBMs from imposing gag clauses that restrict pharmacists from telling consumers when purchasing a drug out of pocket, rather than with insurance, would save money.[9]

- New regulations requiring Medicare Part D plans, starting in 2021, to include drug price increases and lower-cost therapeutic alternatives in their members' explanations of benefits, and supply an electronic tool to inform prescribers of lower-cost therapies at the point of service.[10]

- A proposed rule that solicits feedback on requiring commercial plans to provide estimates to members regarding prices and cost-sharing for different drugs and services.[11]

- As discussed below, CMS attempted to require manufacturers to include list prices in direct-to-consumer television advertisements, but was blocked by a federal court.

Value-Based Care

The administration has supported value-based payment models for prescription drugs, particularly in the Medicaid program. Since June 2018, CMS has approved three state plan amendments authorizing states to enter into contracts with manufacturers that tie Medicaid reimbursement to certain drugs' outcomes.[12]

CMS also approved proposals by Louisiana and Washington to implement subscription-based models for purchasing expensive Hepatitis C drugs.[13] Commonly referred to as the Netflix model, this arrangement allows the state to pay a flat fee to a manufacturer in exchange for unlimited access to its Hepatitis C drug over a certain period.[14]

While value-based arrangements provide states with an innovative approach to managing Medicaid drug spending, the long-term impact of such models is unclear.[15]

FDA Initiatives

Drug prices generally do not fall within the U.S. Food and Drug Administration's jurisdiction, but the agency has taken some modest administrative steps to encourage competition, including releasing various action plans and guidance materials to promote the development of lower-cost generics and biosimilars.[16]

The FDA also has sought to discourage manufacturers from engaging in what many perceive to be anti-competitive behaviors. Examples include issuing new guidances to prevent brand-name manufacturers from using the FDA's citizen petition process or negotiations over shared risk evaluation and mitigation strategies to delay generic competition,[17] as well as publishing the names of companies that block generic manufacturers from obtaining samples necessary to reverse engineer a brand-name drug.[18]

Policy Retreats and Defeats

Medicare-Protected Classes

In conjunction with expanding prior authorization and step therapy within the Medicare-protected classes, CMS also initially proposed granting Part D plans the ability to exclude certain protected drugs from their formularies altogether. A November 2018 proposed rule would have allowed plans to exclude a protected drug from their formularies if (1) the drug was merely a new formulation of an existing single-source drug or (2) the drug's list price rose faster than inflation.[19]

The proposal, however, received pushback from drug makers, patient and provider groups, and members of Congress concerned that scaling back the protected classes could adversely affect patients suffering from serious conditions.[20]

The Trump administration ultimately backed off and did not include the exclusion proposal in its May 2019 final rule,[21] succumbing to the same political pressure that compelled the Obama administration to drop its proposal in 2014 to eliminate three of the six protected classes.[22] CMS's second defeat on this issue in just five years suggests that the protected classes likely are safe for the near future.

Anti-Kickback Statute and Rebates

Just two months after abandoning its protected class reform, the administration withdrew its proposed rule to amend the Anti-Kickback Statute's regulatory safe harbors to encourage plans and PBMs to share rebates received from drug manufacturers directly with Medicare and Medicaid beneficiaries.[23] Specifically, the rule would have made three changes:

- Narrowed the existing regulatory discount safe harbor to exclude manufacturer rebates on prescription drugs offered to Medicare and Medicaid plans and the PBMs dealing on their behalf;

- Established a new safe harbor to protect discounts offered by manufacturers that are shared with the beneficiary at the point of sale; and

- Established a new safe harbor for service fees paid to PBMs by manufacturers that are not based on volume.[24]

Although the proposed rule would not have directly regulated the price-setting activities of manufacturers, the U.S. Department of Health and Human Services contended that the rule would reduce beneficiaries' out-of-pocket costs by redirecting rebates to the point of sale, while removing the incentive for manufacturers to keep list prices (and rebates) high to secure more favorable formulary placement for their products from PBMs and plans.[25]

The prospect that Part D premiums would rise to account for the loss of rebate revenue, and HHS's own estimate of a 10-year increase in federal spending of as much as $196 billion, together with the disruption to existing business practices and the uncertainty about whether any reduction in list prices would result, likely will keep this proposal from becoming law any time soon.[26]

Price Transparency in Television Ads

In May 2019, CMS issued its final rule requiring manufacturers include list prices in television advertisements promoting drugs that are covered by Medicare and Medicaid.[27] In July, a federal district court vacated the rule on the grounds that it exceeded HHS's regulatory authority, without opining on whether it constituted compelled speech under the First Amendment.[28]

Even if HHS can convince the U.S. Court of Appeals for the District of Columbia Circuit on appeal that it has the authority to issue such a rule, the plaintiffs likely have the upper hand with respect to the First Amendment arguments.[29]

International Trade

Most recently, the administration scored an ironic win when House Democrats succeeded at removing extended market exclusivity for biologics from the proposed United States-Mexico-Canada trade agreement.[30] As originally negotiated, the USMCA would have extended exclusivity periods for biologics to 10 years in Canada and Mexico, which currently grant eight and five years, respectively, compared to 12 years in the United States.[31] The longer exclusivity periods would have given brand makers a longer period to charge higher prices abroad, aligning with the president's desire to reduce free-riding by foreign governmental payers.

House Democrats objected that this was a giveaway to the drug industry, and to obtain their support, the administration backed off. But the effect of the change may be to give a boost to biosimilar makers, which should ultimately lower prices.[32] The House passed the new agreement before Christmas, and the Senate is expected to vote on it in early 2020.[33]

Proposals to Watch in 2020

Importation

In July, the administration proposed two new pathways for importing certain drugs originally intended for foreign markets where they are generally available at lower prices.[34] The administration's embrace of importation — an idea historically championed by Democrats[35] — represents a surprising reversal of both the current and past administrations' long-standing opposition to importation.[36]

After the president publicly directed Azar to help the state of Florida with its efforts to pursue wholesale importation,[37] HHS proposed the following pathways:

- Pathway 1 would authorize demonstration projects developed by states to import certain drugs from Canada. To receive the FDA's approval, states would need to show that the program would ensure consumer safety and achieve cost savings. States would not be permitted to import controlled substances, biologics or drugs subject to the FDA's risk evaluation and mitigation strategies program.[38]

- Pathway 2 would permit manufacturers to import their own drugs that were originally manufactured and intended to be marketed in a foreign country and offer them for

sale at a lower price in the United States under different national drug codes. This pathway would be open to a broader range of drugs, including biologics.[39]

By releasing a proposed rule and draft guidance in December, the administration potentially has teed up both pathways to be finalized at some point in 2020. Multiple states already have expressed interest.[40]

While importation comes as a major reversal for HHS, the policy shift likely will have only a limited impact on drug prices. Canada is a relatively small prescription drug market, which limits the degree to which states can rely on importation.[41] The Canadian government likely will try to impede importation to protect its citizens' access to drugs, especially since manufacturers are unlikely to want to sell more drugs to Canada to replace diverted quantities.[42] Likewise, established Canadian wholesalers are not eager to upset either manufacturers or the Canadian government by engaging in importation.[43]

The second pathway also seems unlikely to have much of an effect. By allowing companies to import the same drugs under different NDCs, the administration contends that manufacturers could avoid contractual obligations with PBMs that manufacturers have cited as preventing them from offering the same product at a lower price.[44] It is unclear, though, why manufacturers would voluntarily make widespread use of this pathway.

International Reference Pricing

In October 2018, the administration announced what is arguably its most consequential proposal thus far: a mandatory Medicare Part B demonstration project that would use an international pricing index to pay for select single-source drugs and biologics.[45] Tying domestic prices to the prices paid in other countries that engage in more aggressive price regulation than the United States represents a remarkable reversal from the blueprint, which expressly criticized other nations' use of price controls and international reference pricing.[46] The original proposal had three major parts:

- Vendor-Based Distribution: Under the current buy-and-bill system, providers assume the risk of acquiring Part B drugs and are later reimbursed by Medicare for the drug's average sales price, or ASP, plus 6%.[47] Under the proposal, vendors, such as PBMs, would contract with CMS to serve as middlemen who would take on the risk of buying drugs and then supply them to providers.

- International Reference Pricing: CMS would reimburse the vendors for each drug at a rate tied to the average price of the drug in select countries.[48] After a five-year phase-in, reimbursement would be equal to 126% of the international pricing index. Medicare currently pays on average 180% of what other countries pay.[49]

- Eliminate ASP Plus 6%: Since providers no longer purchase the drugs themselves, the proposal would replace the average sales price plus 6% reimbursement with a fixed add-on fee for each drug administered, regardless of the drug's cost. Proponents argue a fixed fee would remove the incentive for providers to use more expensive drugs that result in a larger 6% add-on payment.[50]

Despite rumors throughout 2019 that a proposed rule was imminent,[51] it remains under review at the Office of Management and Budget and its details are not public.[52] Administration officials have hinted that the proposed rule may be even more aggressive than the original proposal, taking a most-favored-nation approach, setting Medicare reimbursement at the lowest price paid in select countries, as opposed to the average price.[53]

Although an international reference pricing demonstration project likely would be the most significant action that could come out of the Trump administration this year, there are reasons to be skeptical. First, many commentators have long speculated that the proposal primarily was intended as a negotiating tactic to drive the drug industry, as well as congressional Republicans, to the table.[54]

Second, the administration may be concerned about the lack of support among congressional Republicans.[55] And such a rule would face significant operational and legal challenges. The proposal deferred on many important details,[56] and industry likely would sue on the grounds that it is inconsistent with current law and exceeds CMS' demonstration authority.[57]

Untested Authorities: Compulsory Licensing

The Democratic presidential debates have highlighted two additional potential approaches, under which the government would exercise authority not heretofore applied on a broad scale to disregard patents and license brand-name drugs to other manufacturers. There is so far no indication that the Trump administration would embrace either the Bayh-Dole Act[58] or Section 1498 of the Public Health Service Act[59] in this way,[60] and certainly any such attempt would face stiff challenge in the courts.

The 116th Congress

While both Democrats and Republicans appear to agree that Congress ought to do something to address drug prices, divisions between the Democratic House and Republican Senate, and within the parties themselves, have prevented Congress from passing comprehensive legislation.

In 2019, Congress did attach a few less controversial drug pricing reforms to other bills:

- Medicaid Rebates: In April, the bipartisan Right Rebate Act created new penalties for manufacturers that knowingly misclassify brand-name drugs as generics to reduce their obligations under the Medicaid Drug Rebate Program.[61] In September, Congress enacted another reform that will increase MDRP rebate obligations for some brand drugs by removing a pricing benefit that had existed for authorized generics.[62]

- CREATES Act: In December's year-end spending package, Congress finally enacted the bipartisan CREATES Act.[63] The legislation created new causes of action against brand-name companies that refuse to offer samples of drugs on reasonable terms for the purposes of testing and developing generic or biosimilar alternatives. It also

gives FDA more flexibility to approve alternative safety protocols when brand-name companies refuse to allow generic companies to participate in a shared REMS.[64]

While the list of accomplishments for 2019 is short, Congress is poised to take another swing at drug pricing legislation in 2020. The year-end spending bill that included the CREATES Act extended the deadline for a range of must-pass legislation to May 2020 to give congressional leaders more time to build consensus for a drug pricing package that can be attached.[65]

There are currently three major pieces of legislation that should influence those conversations. From the most ambitious to the least, those bills are: (1) Pelosi's sweeping government negotiation bill that passed the House in December, but has no prospects in the Republican Senate; (2) the Senate Finance Committee's bipartisan bill crafted by Chairman Chuck Grassley, R-Iowa; and (3) a package of bipartisan, largely noncontroversial, and thus relatively more modest proposals, crafted by Rep. Greg Walden, R-Ore..

The Pelosi Bill

In December, all House Democrats and two Republicans voted to pass Pelosi's bill, H.R. 3, which, if enacted, would dramatically alter the U.S. drug market.[66] Most notably, H.R. 3 would require HHS to negotiate prices directly with manufacturers for a minimum of 50 drugs, and up to as many as 250 drugs, per year.[67]

The negotiated price must not exceed 120% of the average price paid in six reference countries and must be offered to both federal health care programs and commercial plans. To drive manufacturers to the negotiating table, H.R. 3 would impose steep excise taxes on companies that refuse to negotiate or fail to agree to a price at or below the international reference price.[68]

H.R. 3 also includes variations of two of the major proposals in the Grassley bill. First, it would revamp the Medicare Part D benefit by capping beneficiaries' annual out-of-pocket drug spending (currently, there is no such cap), eliminating the coverage gap or donut hole, and expanding brand-name manufacturers' obligations to provide discounts.

Second, H.R. 3 would require manufacturers to pay rebates to Medicare Parts B and D for the amount by which a drug's list price increases faster than inflation. Unlike the Grassley bill, H.R. 3 would create a process for extending such rebates to the commercial market as well.[69]

The White House ultimately opposed H.R. 3,[70] despite, as House Democrats like to highlight, Trump's support for government negotiations during the 2016 campaign.[71]

The Grassley Bill

In the Senate, Chairman Grassley's Prescription Drug Pricing Reduction Act has emerged as the leading bill.[72] Negotiated with committee Democrats and endorsed by the White House, the bipartisan package was reported out of the Finance Committee in July by a vote of 19 to 9. The bill, however, divided the committee's Republicans 6 to 9.[73]

Like H.R. 3, the PDPRA would require manufacturers to pay rebates to Medicare Parts B and D when a product's list price rises faster than inflation.[74] The inflationary rebates likely

are the bill's most consequential provisions — accounting for roughly $68 billion in savings to the Medicare program over 10 years[75] — as well as its most controversial.

In addition to the Medicare rebate provisions, the PDPRA contains a wide range of drug pricing reforms. Like H.R. 3, the bill would redesign the Medicare Part D benefit. It also would raise the cap on manufacturer's MDRP rebate obligations, impose new manufacturer price reporting obligations, authorize new Medicaid value-based payment models and tweak various federal drug reimbursement methodologies.[76]

The Walden Bill

Lastly, Republican Energy and Commerce Committee ranking member Greg Walden has introduced his own package of drug pricing policies, H.R. 19.[77] H.R. 19 avoids more controversial policies, such as Medicare rebates and price negotiation, and instead packages together an assortment of more modest, bipartisan proposals.

For example, the bill contains multiple transparency measures, including requiring list prices in direct-to-consumer advertisements; many of the tweaks to federal health care programs included in the Grassley bill; various FDA reforms; and measures to crack down on pay-for-delay agreements. Notably, H.R. 19 eliminates the MDRP rebate cap entirely and includes a similar Medicare Part D benefit redesign.[78]

2020 Forecast

In the run-up to the next legislative deadline in May, each of these bills likely will play some role in the ongoing drug pricing debate. While Pelosi's government negotiation provisions are going nowhere in the Senate, her bill will remain a popular talking point for House Democrats and serves as an instructive marker for the Democratic Party's increasingly aggressive posture towards the drug industry.[79]

Grassley remains committed to courting his Republican colleagues to get his bipartisan package over the finish line. However, the continued angst about Medicare inflationary rebates as price controls, and Sen. Mitch McConnell's lack of support underscore the challenges he faces.[80]

As Grassley has acknowledged, his bill's prospects may depend on whether Trump and his administration are willing to pressure Senate Republicans to back the package.[81] Thus far, there is little evidence that Trump has made Grassley's bill a priority.[82]

In the absence of a sustained push by the White House, the Walden bill likely is left as the most viable option. Without getting significantly more aggressive policies in return, Democrats are unlikely to give congressional Republicans and the White House a drug pricing win by allowing the Walden bill to pass on its own.

That said, prognosticators can look to the Walden bill for an instructive list of more modest, less controversial and bipartisan drug pricing measures that could catch a ride on another legislative package. For example, raising or eliminating the MDRP rebate cap recently has been discussed as an option.[83] Likewise, some form of redesigning the Medicare Part D benefit, especially capping beneficiaries' out-of-pocket costs, could attract bipartisan interest.

The 50 States

While Congress largely punted to 2020 on drug pricing, state legislatures last year added to their growing list of enacted drug pricing laws. According to the National Academy for State Health Policy, more than 300 drug pricing bills were introduced in state legislatures in 2019 and 37 states enacted at least one such bill.[84] Some of the most noteworthy measures include:

- Regulating PBMs: Many of the laws enacted in 2019 targeted PBMs. Such laws include requiring PBMs to register with the state; prohibiting PBMs and plans from using "gag clauses;" establishing new reporting requirements; and banning spread pricing.[85] The volume of bills regulating PBMs and plans suggests that state legislators have been at least somewhat receptive to the drug industry's efforts to cast the blame for higher prices on middlemen in the distribution chain.

- Price Reporting: Transparency measures remain popular with state legislators. In 2019, at least six states enacted new manufacturer price reporting bills.[86] As with federal transparency proposals, these laws have no direct effect on price setting, but rather seek to shame manufacturers into lowering prices.

- Wholesale Importation: Legislators introduced drug importation bills in at least 19 states in 2019. Thus far, four states have enacted laws to seek federal permission to establish wholesale importation programs.[87]

- Rate-Setting Boards: Federal courts have made clear that states have limited authority to regulate directly what manufacturers may charge.[88] In response, legislators in at least nine states introduced bills in 2019 that would instead create affordability review boards to regulate what purchasers may pay for certain drugs.[89] Maryland and Maine passed watered-down versions of their bills, which ultimately created boards with merely research and advisory functions, but no immediate rate-setting powers.[90] If a state establishes a board with such powers, the drug industry almost certainly will try to block such a law through the courts.

Conclusion

Over the past few years, the drug industry has faced unprecedented scrutiny from the media, politicians and the public. The year 2020 should be no different. The Trump administration continues to take steps in the direction of implementing parts of its blueprint, and may finalize in the coming year at least two groundbreaking changes to federal policy: endorsing wholesale importation and adopting international reference pricing for certain drugs paid for by Medicare.

Trump's Democratic rivals for the White House likely will make the case that they would be even more aggressive in taking on the drug industry. Congress has not given up hope on passing a comprehensive drug pricing package with more noise surely to come in the run-up to the next must-pass legislative deadline in May. And, finally, state legislatures have started to reconvene for the new year, eager to pick up where they left off.

So, if you haven't heard lately that drug prices are too high, you're almost certainly going to hear it in 2020.

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[1] See Tami Luhby, Democrats and Republicans Promised to Lower Drug Prices, Instead They've Gone Up Again, CNN (Jan. 5, 2020), https://www.cnn.com/2020/01/05/politics/2020-drug-price-increases/index.html.

[2] Denise Roland, At $2 Million, New Novartis Drug is Priciest Ever, The Wall Street Journal (May 24, 2019), https://www.wsj.com/articles/at-2-million-new-novartis-drug-is-priciest-ever-11558731506.

[3] U.S. Department of Health and Human Services., American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (herein "The Blueprint").

[4] Id.

[5] In August 2018, CMS announced the decision via a letter to Medicare Advantage plans. Letter from Administrator Seema Verma to Medicare Advantage Organizations, Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, CMS.gov (Aug. 7, 2018), https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf. This guidance reversed the agency's prior position during the Obama administration that the Medicare statute prohibits step therapy for Part B drugs. See Letter from Director Danielle R. Moon to Medicare Advantage Organizations, Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services, CMS.gov (Sept. 17, 2012), https://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf. CMS codified its new position for 2020 and future years in a May 2019 final rule. 84 Fed. Reg. 23832, 23835 (May 23, 2019).

[6] The six protected classes are (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. 42 U.S.C. §1395w-104(b)(3)(G).

[7] 84 Fed. Reg. at 23832.

[8] See, e.g., Thomas Sullivan, Transparency Push in Pharma: Will it Result in Lower Prices to Patients?, Policy & Medicine (Aug. 18, 2019), https://www.policymed.com/2019/08/transparency-push-in-pharma-will-it-result-in-lower-prices-to-patients.html; Kelly Davio, State-Level Drug Price Transparency Laws Miss the Mark, Say Researchers, The Center for Biosimilars (Oct. 1, 2019), https://www.centerforbiosimilars.com/news/statelevel-drug-price-transparency-

laws-miss-the-mark-say-researchers.

[9] Patient Right to Know Drug Prices Act, S. 2554, 115th Cong. (2018) (enacted); Know the Lowest Price Act, S. 2553, 115th Cong. (2018) (enacted).

[10] 84 Fed. Reg. at 23833, 23848.

[11] 84 Fed. Reg. 65464 (Nov. 27, 2019).

[12] Centers for Medicare & Medicaid Services, CMS Approves State Proposal to Advance Specific Value-Based Arrangements with Drug Makers (June 27, 2018), https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers (Oklahoma); Medicaid State Plan Amendment, Medicaid.gov (Nov. 14, 2018), https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf (Michigan); Medicaid State Plan Amendment, Medicaid.gov (Feb. 25, 2019), https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CO/CO-18-0044.pdf (Colorado).

[13] Centers for Medicare & Medicaid Services, CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid (June 26, 2019), https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified; Centers for Medicare & Medicaid Services, CMS Approves Washington State Plan Amendment Proposal to Allow Supplemental Rebates Involving a "Subscription" Model for Prescription Drug Payment in Medicaid (June 12, 2019), https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving.

[14] See Ted Alcon, Louisiana's Deal for Hepatitis C Drugs May Serve as Model, The Wall Street Journal (Sept. 13, 2019), https://www.wsj.com/articles/louisianas-deal-for-hepatitis-c-drugs-may-serve-as-model-11568347621.

[15] Thus far, states have encountered various challenges in setting up outcomes-based contracts with manufacturers, while subscription-based models may only work for a small number of drugs with market conditions similar to those of Hepatitis C drugs. See, e.g., Nicholas Fiore et al., Novel State Payment Models for Prescription Drugs: Early Implementation Successes and Challenges, Duke Margolis Center for Health Policy, 4 (Sept. 2019), https://healthpolicy.duke.edu/sites/default/files/u31/novel_state_payment_models_final_revised_091219.pdf; Mark Trusheim and Peter B. Bach, Next Steps for Netflix: Can 'All You Can Treat' Contracts Work Beyond Hepatitis C?, Health Affairs (Sept. 25, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190924.559225/full.

[16] See, e.g., FDA Tackles Drug Competition to Improve Patient Access, FDA.gov (June 27, 2017), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm564725.htm; Biosimilars Action Plan: Balancing Innovation and Competition, FDA.gov (July 2018), https://www.fda.gov/media/114574/download; FDA In Brief: FDA issues 63 product-specific guidances to promote generic drug access and drug price competition, FDA.gov (Nov. 28, 2018), https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm626952.htm.

[17] See, e.g., Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act: Guidance for Industry, FDA.gov (Oct. 2018), https://www.fda.gov/downloads/Drugs/Guidance

ComplianceRegulatoryInformation/Guidances/UCM622235.pdf; Waivers of the Single, Shared System REMS Requirement: Guidance for Industry, FDA.gov (June 2018), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf.

[18] Reference Listed Drug (RLD) Access Inquiries, FDA.gov (last updated Sept. 24, 2019), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rld-access-inquiries.

[19] 83 Fed. Reg. 62152 (Nov. 30, 2018).

[20] See, e.g., Mindy Yochelson, Leave Medicare Drug Coverage Alone, Patient Advocates Say, Bloomberg Law (Nov. 29, 2018), https://news.bloomberglaw.com/health-law-and-business/leave-medicare-drug-coverage-alone-patient-advocates-say.

[21] 84 Fed. Reg. at 23832.

[22] See Jeff Overley, Feds Scrap Controversial Medicare Part D Changes, Law360 (Mar. 10, 2014), https://www.law360.com/health/articles/516919/feds-scrap-controversial-medicare-part-d-changes.

[23] 84 Fed. Reg. 2340 (Feb. 6, 2019); Dan Diamond, White House Kills Drug Rebate Rule, Politico (July 11, 2019), https://www.politico.com/newsletters/politico-pulse/2019/07/11/white-house-kills-drug-rebate-rule-678684.

[24] 84 Fed. Reg. at 2347-50. For a more detailed summary of the proposed rule, see Tom Bulleit et al., A First Look at New HHS Prescription Drug Safe Harbors, Law360 (Feb. 15, 2019), https://www.law360.com/articles/1128564/a-first-look-at-new-hhs-prescription-drug-safe-harbors.

[25] See U.S. Department of Health and Human Services, Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients (Jan. 31, 2019), https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html.

[26] See 84 Fed. Reg. at 2357-59; Rachel Cohrs, White House Kills Rebate Rule Because It Would Raise Premiums, InsideHealthPolicy (July 11, 2019), https://insidehealthpolicy.com/daily-news/white-house-kills-rebate-rule-because-it-would-raise-premiums.

[27] 84 Fed. Reg. 20732 (May 10, 2019).

[28] Merck & Co. v. United States Dep't of Health and Human Servs., 385 F. Supp. 3d 81 (D.D.C. 2019).

[29] See Emily Field, 3 Takeaways from Nixing of Drug Pricing Rule, Law360 (July 10, 2019), https://www.law360.com/articles/1176459/3-takeaways-from-nixing-of-drug-pricing-rule. Likewise, if Congress were to pass legislation giving HHS express authority to issue such regulations, the initiative would remain vulnerable to a First Amendment challenge.

[30] Nathaniel Weixel, Democrats Declare Victory for Eliminating Drug Protections in Trade

Deal, The Hill (Dec. 10, 2019), https://thehill.com/policy/healthcare/473953-democrats-declare-victory-for-eliminating-drug-protections-in-trade-deal.

[31] Nathaniel Weixel, Trump Targets Drug Protections to Save Trade Deal, The Hill (Dec. 3, 2019), https://thehill.com/policy/healthcare/472913-trump-targets-drug-protections-to-save-trade-deal.

[32] In fact, press reports suggest that Mr. Trump rejected congressional Republicans' pleas to preserve the provision because he feared it would undercut his administration's messaging regarding its commitment to lowering drug prices. See Jonathan Swan and Caitlin Owens, Trump's Fine with Ditching USMCA Prescription Drug Provision, Axios (Dec. 10, 2019), https://www.axios.com/trumps-fine-with-ditching-usmca-prescription-drug-provision-e455ba8e-fb2f-4073-aa5e-696e20bc4283.html.

[33] Evie Fordham, Senate Could Approve USMCA as Early as Friday: Navarro, Fox Business (Jan. 5, 2020), https://www.foxbusiness.com/markets/usmca-senate-fast-track-navarro.

[34] U.S. Department of Health and Human Services, HHS Announces New Action Plan to Lay Foundation for Safe Importation of Certain Prescription Drugs (July 31, 2019), https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html.

[35] For example, 34 Democrats, but only 12 Republicans in the U.S. Senate voted for a 2017 budget amendment related to importation of drugs from Canada. See Klobuchar Amdt. No. 178 (Jan. 11, 2017), https://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=115&session=1&vote=00020.

[36] See, e.g., Mike Leavitt, Why Drug Importation is Flawed Policy, Morning Consult (Mar. 20, 2017), https://morningconsult.com/opinions/drug-importation-flawed-policy/ ("In fact, my predecessors and successors [as HHS Secretary] from both political parties, along with multiple FDA Commissioners, have consistently found that drug importation carries potential dangers that can't be ignored."). See also Alex Azar, Remarks on Drug Pricing Blueprint, HHS.gov (May 14, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html (dismissing importation as a "gimmick").

[37] Alexandra Glorioso, Trump Directs Azar to Work on Florida Drug Import Plan, Politico (May 6, 2019), https://www.politico.com/states/florida/story/2019/05/06/trump-directs-azar-to-work-on-florida-drug-import-plan-1008710.

[38] 84 Fed. Reg. 70796 (Dec. 23, 2019).

[39] Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act: Draft Guidance for Industry, HHS.gov (Dec. 2019),: https://www.hhs.gov/sites/default/files/importation-of-certain-fda-approved-human-presciption-drugs-including-biological-products.pdf.

[40] Ariel Cohen, New York Gov. Cuomo to Describe Canadian Drug Importation Plan, InsideHealthPolicy (Dec. 27, 2019), https://insidehealthpolicy.com/daily-news/new-york-gov-cuomo-describe-canadian-drug-importation-plan.

[41] According to Canada's acting ambassador to the United States, Canada represents only

two percent of the global pharmaceutical market, while the United States comprises 44 percent. Robert King, Canadian Ambassador Tells White House Drug Import Plan Unworkable, Not Enough Supplies, FierceHealthcare (Nov. 4, 2019), https://www.fiercehealthcare.com/payer/canadian-ambassador-tells-white-house-drug-import-plan-unworkable-not-enough-supplies.

[42] Id.; Megan Cerullo, Experts 'Not Optimistic' About Trump Plan to Import Drugs from Canada, CBS News (Dec. 20, 2019), https://www.cbsnews.com/news/prescription-drugs-imported-from-canada-wont-lower-prices-for-american-consumers-experts-say/.

[43] Natalie Obiko Pearson and Simran Jagdev, Trump's Canada Drug Import Plan Can't Happen Without Big Pharma, Bloomberg (Aug. 13, 2019), https://www.bloomberg.com/news/articles/2019-08-13/trump-s-canada-drug-import-plan-can-t-happen-without-big-pharma. See also Allison Martell, Canadian Drug Distributors Say No to Trump Import Plan, Reuters (Dec. 20, 2019), https://www.reuters.com/article/us-usa-healthcare-canada/canadian-drug-distributors-say-no-to-trump-import-plan-idUSKBN1YO24O.

[44] U.S. Department of Health and Human Services, Safe Importation Action Plan, 3 (July 31, 2019), https://www.hhs.gov/about/news/2019/07/31/hhs-new-action-plan-foundation-safe-importation-certain-prescription-drugs.html.

[45] 83 Fed. Reg. 54546 (Oct. 30, 2018).

[46] The Blueprint, supra note 3 at 14-15.

[47] Fact Sheet: ANPRM International Pricing Index Model for Medicare Part B Drugs, CMS.gov (Oct. 25, 2018), https://www.cms.gov/newsroom/fact-sheets/anprm-international-pricing-index-model-medicare-part-b-drugs.

[48] CMS proposed using an index composed of twelve European nations, Canada, and Japan. 83 Fed. Reg. at 54557.

[49] U.S. Department of Health and Human Services, What You Need to Know About President Trump Cutting Down on Foreign Freeloading (Oct. 25, 2018), https://www.hhs.gov/about/news/2018/10/25/ipi-policy-brief.html.

[50] See, e.g., MedPAC, Chapter 3: Medicare Payment Strategies to Improve Price Competition and Value for Part B Drugs, 56 (June 2019), http://www.medpac.gov/docs/default-source/reports/jun19_ch3_medpac_reporttocongress_sec.pdf?sfvrsn=0.

[51] See, e.g., Robert King, Regulatory Agenda Lays Out Timetable for Major Rules on Drug Pricing, Interoperability, FierceHealthcare (Nov. 20, 2019), https://www.fiercehealthcare.com/hospitals-health-systems/regulatory-agenda-lays-out-timetable-for-major-rules-drug-pricing.

[52] Office of Information and Regulatory Affairs, View Rule: HHS/CMS, RIN 0938-AT88, Office of Management and Budget (last visited Jan. 5, 2020), https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0938-AT88.

[53] See Peter Sullivan, Trump Officials Making Changes to Signature Drug Pricing Proposal,

Azar Says, The Hill (Nov. 13, 2019), https://thehill.com/policy/healthcare/470230-trump-officials-making-changes-to-signature-drug-pricing-proposal-azar-says.

[54] See, e.g., Peter Sullivan, Key Trump Proposal to Lower Drug Prices Takes Step Forward, The Hill (June 21, 2019), https://thehill.com/policy/healthcare/449740-key-trump-proposal-to-lower-drug-prices-takes-step-forward.

[55] Lev Facher, 'Don't be a Bernie Bro': Inside Conservatives' Brazen Campaign to Sabotage Trump's Signature Drug Pricing Plan, Stat (July 29, 2019), https://www.statnews.com/2019/07/29/conservative-campaign-against-drug-prices/.

[56] See, e.g., Tom Bulleit et al., The Trump Administration's Latest Drug Pricing Initiatives, Law360 (Jan. 14, 2019), https://www.law360.com/articles/1118068/the-trump-administration-s-latest-drug-pricing-initiatives (noting that CMS abandoned a similar, but voluntary, competitive acquisition program in 2009 and discussing potential operational challenges, including whether there will be sufficient participation by vendors, how CMS will fulfill its promise to ensure providers are held harmless despite the shift from ASP+6% to an add-on fee, and what steps the agency will take to protect beneficiaries' access if manufacturers refuse to sell to vendors at significantly discounted prices).

[57] See, e.g., Sarah Owermohle and Sarah Karlin-Smith, Unanswered Questions on Trump's Drug-Pricing Plan, Politico Prescription Pulse (Oct. 29, 2018), https://www.politico.com/newsletters/prescription-pulse/2018/10/29/unanswered-questions-on-trumps-drug-pricing-plan-391874; Jeff Overley, 5 Takeaways as Trump Eyes Cut to Medicare Drug Payments, Law360 (Oct. 25, 2018), https://www.law360.com/articles/1095721/5-takeaways-as-trump-eyes-cut-to-medicare-drug-payments.

[58] 35 U.S.C. §203. See also John R. Thomas, March-In Rights under the Bayh-Dole Act, Congressional Research Service, 1 (Aug. 22, 2016), https://fas.org/sgp/crs/misc/R44597.pdf.

[59] 28 U.S.C. §1498. See also Hannah Brennan et al., A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 Yale J.L. & Tech. 275, 302-307 (2017).

[60] See Shefali Luthra, In the Battle to Control Drug Costs, Old Patent Laws Get New Life, Kaiser Health News (Oct. 5, 2018), https://khn.org/news/in-the-battle-to-control-drug-costs-old-patent-laws-get-new-life/.

[61] Medicaid Services Investment and Accountability Act, H.R. 1839, 116th Cong. (enacted Apr. 18. 2019) (containing the Right Rebate Act, S. 205, 116th Cong. (2019)); Office of U.S. Senator Chuck Grassley, Grassley, Wyden Praise Congressional Passage of Right Rebate Act (Apr. 2, 2019), https://www.grassley.senate.gov/news/news-releases/grassley-wyden-praise-congressional-passage-right-rebate-act.

[62] Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, H.R. 4378, 116th Cong. (enacted Sept. 27, 2019).

[63] Further Consolidated Appropriations Act, H.R. 1865, 116th Cong. (enacted Dec. 20, 2019) (containing the CREATES Act, S. 340, 116th Cong. (2019)).

[64] Id. See also Office of U.S. Senator Patrick Leahy, The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017 (last visited Jan. 6, 2020), https://www.leahy.senate.gov/imo/media/doc/CREATES%20Press%20Background%20Materials.pdf.

[65] H.R. 1865, supra note 63; Paige Winfield Cunningham, The Health 202: Congress Failed to Pass a Drug Pricing Overhaul. So it Set Another Deadline., The Washington Post (Dec. 17, 2019), https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/12/17/the-health-202-congress-failed-to-pass-a-drug-pricing-overhaul-so-it-set-another-deadline/5df7c57a88e0fa32a5140777/.

[66] Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019).

[67] HHS would negotiate prices for a minimum of 25 drugs for 2023. For 2024 and subsequent years, HHS would be subject to a 50-drug minimum. Id.

[68] Id.

[69] Id.

[70] See Office of Management and Budget, Statement of Administration Policy: H.R. 3 (Dec. 10, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/12/SAP_HR-3.pdf; Sarah Karlin-Smith, How Trump and the Democrats Parted Ways on Lowering Drug Prices, Politico (Dec. 11, 2019), https://www.politico.com/news/2019/12/11/donald-trump-democrats-drug-pricing-082545.

[71] See Peter Sullivan, Trump Draws Ire after Retreat on Drug Prices Pledge, The Hill (Nov. 24, 2019), https://thehill.com/policy/healthcare/471735-trump-draws-ire-after-retreat-on-drug-prices-pledge.

[72] Chairman Grassley and Ranking Member Wyden released the most recent version of the PDPRA in early December. This version is available at U.S. Senate Finance Committee, Grassley, Wyden Release Updated Prescription Drug Pricing Reduction Act, Reach Agreement on Health Extenders (December 6, 2019), https://www.finance.senate.gov/chairmans-news/grassley-wyden-release-updated-prescription-drug-pricing-reduction-act-reach-agreement-on-health-extenders. The December bill updated the formal legislative text that was introduced as S. 2543 in September, which is available at U.S. Senate Finance Committee, S. 2543: The Prescription Drug Pricing Reduction Act of 2019 (Sept. 25, 2019), https://www.finance.senate.gov/legislation/details/the-prescription-drug-pricing-reduction-act-of-2019. The original proposal voted on by the Finance Committee in July, as well as other materials from the markup, are available at U.S. Senate Finance Committee, Open Executive Session to Consider an Original Bill Entitled The Prescription Drug Pricing Reduction Act of 2019 (July 25, 2019), https://www.finance.senate.gov/hearings/open-executive-session-to-consider-an-original-bill-entitled-the-prescription-drug-pricing-reduction-act-of-2019.

[73] Id.

[74] Id.

[75] Congressional Budget Office, The Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (July 24, 2019) (preliminary estimate), https://www.cbo.gov/system/files/2019-

07/PDPRA_preliminary_estimate.pdf.

[76] U.S. Senate Finance Committee, Grassley, Wyden Release Updated PDPRA, supra note 72.

[77] Lower Costs, More Cures Act, H.R. 19, 116th Cong. (2019). Shortly before Christmas, a group of six Senate Republicans, including three Finance Committee members, introduced a similar companion bill (S. 3129). Lower Costs, More Cures Act, S. 3129, 116th Cong. (2019). The bill's introduction was seen as further evidence of dissatisfaction among Senate Republicans with the Grassley bill. Ariel Cohen, Grassley Downplays Fellow GOP Senators' Drug Pricing Bill, InsideHealthPolicy (Dec. 20, 2019), https://insidehealthpolicy.com/daily-news/grassley-downplays-fellow-gop-senators%E2%80%99-drug-pricing-bill.

[78] H.R. 19, supra note 77.

[79] Karlin-Smith, supra note 70.

[80] See Marianne Levine and Sarah Karlin-Smith, Senate Quicksand Engulfs a Bipartisan Plan that Trump Backs, Politico (Dec. 1, 2019), https://www.politico.com/news/2019/12/01/prescription-drugs-bill-trump-074077; Peter Sullivan, McConnell, Grassley at Odds Over Trump-Backed Drug Bill, The Hill (Dec. 6, 2019), https://thehill.com/policy/healthcare/473316-mcconnell-grassley-at-odds-over-trump-backed-drug-bill.

[81] See Levine and Karlin-Smith, supra note 80.

[82] See, e.g., John Wilkerson et al., Grassley Says McConnell Blocking GOP Support for Drug Pricing Bill, InsideHealthPolicy (Dec. 18, 2019), https://insidehealthpolicy.com/daily-news/grassley-says-mcconnell-blocking-gop-support-drug-pricing-bill.

[83] John Wilkerson, Lawmakers Consider Paying for DSH Policy with Medicaid Drug Rebates, InsideHealthPolicy (Nov. 22, 2019), https://insidehealthpolicy.com/inside-drug-pricing-daily-news/lawmakers-consider-paying-dsh-policy-medicaid-drug-rebates.

[84] See National Academy for State Health Policy, State Prescription Drug Legislative Tracker 2019 (Dec. 5, 2019), https://nashp.org/wp-content/uploads/2019/09/Rx-end-of-year-Tracker-2019-12.5.2019.pdf. NASHP regularly updates their state legislative tracker, and has posted the final trackers from 2015 through 2018, here: NASHP, State Legislative Action to Lower Pharmaceutical Costs, https://nashp.org/rx-legislative-tracker-2019/.

[85] See NASHP, State Prescription Drug Legislative Tracker 2019 (as of Dec. 5, 2019), supra note 84.

[86] Id.

[87] Those states are Colorado, Florida, Maine, and Vermont. Id.

[88] See, e.g., Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664 (4th Cir. 2018) (striking down under the Dormant Commerce Clause a Maryland statute that prohibited "unconscionable increase[s]" in price for essential off-patent or generic drugs); Biotechnology Indus. Org. v. Dist. of Columbia, 496 F.3d 1362 (Fed. Cir. 2007) (invalidating under the Supremacy Clause a Washington, D.C. law that prohibited manufacturers from charging "an excessive price" for patented prescription drugs).

[89] See NASHP, State Prescription Drug Legislative Tracker 2019 (as of Dec. 5, 2019), supra note 84. NASHP has played a leading role in the development of drug affordability review board bills. The organization's model legislation and other resources are available here: National Academy for State Health Policy, Model Legislation, (last visited Jan. 6, 2019), https://nashp.org/policy/prescription-drug-pricing/model-legislation/.

[90] See H.B. 768, 2019 Reg. Sess. (Md. 2019) (enacted May 25, 2019), http://mgaleg.maryland.gov/webmga/frmMain.aspx?id=hb0768&stab=01&pid=billpage&tab=subject3&ys=2019RS; L.D. 1499, 129th Leg., 2019 First Reg. Sess. (Me. 2019) (enacted June 24, 2019), http://legislature.maine.gov/LawMakerWeb/summary.asp?ID=280073010. Under H.B. 768, the Maryland board may acquire rate-setting powers starting in 2022. To do so, the board must receive approval from either the General Assembly's Legislative Policy Committee or both the Governor and Attorney General. If such authority is granted, the board's upper payment limits would apply only to drugs purchased or paid for by state or local governments.