EXECUTIVE SUMMARY

Drug Prices are a hot topic in political circles. Nearly every 2020 presidential candidate has taken a position on controlling prescription drug prices, and nearly 50 pieces of legislation filed in the House and Senate are aimed at addressing the issue.

The Trump Administration has been very vocal on prescription drug prices, initiating several significant regulatory actions aimed at a variety of measures, including prohibiting drug rebates in certain circumstances, as well as requiring that drug prices be listed in various forms of advertisement, including television ads.

A number of States, including Florida, Vermont and Massachusetts are looking at ways to lower the cost of prescription drugs, including allowing Canadian drug importation for their State Medicaid and State prison populations, and even their general populations.

OVERVIEW

Addressing prescription drug prices remains a focus for Congress, the Trump Administration, and now, a growing number of States. So, what’s all the fuss? This white paper summarizes the various factors fueling the drug pricing debate, lays out the various approaches being discussed, and ends with some thoughts on the impact this may have on employer-sponsored health coverage.

FAST INFORMATION: Please see Appendix I which defines many of the concepts underlying the prescription drug price debate.
MAKING SENSE OF THE PRESCRIPTION DRUG PRICE DEBATE

How much is spent on prescription drugs?

The U.S. Department of Health & Human Services (HHS) published a 2016 report stating that total prescription drug spending in the U.S. was about $457 billion (or 16.7% of the overall personal health care expenditures). Of that total, $328 billion (or 71.9%) was for retail drugs and $128 billion (or 28.1%) was for non-retail drugs (i.e., drugs dispensed in doctor and hospital settings). For context, Americans spent $100 billion more on prescription drugs in 2016 than they spent in 2007. That’s roughly a 40% increase in a ten-year period.

In its report, HHS said that the growth in prescription drug expenditures was driven by four factors:

1. 10% by the growth in population;
2. 30% by the increased use of prescription drugs;
3. 30% by general inflation; and
4. 30% by “specific drug price inflation.”

“Specific drug price inflation” resulted from: (1) the use of drugs that were more expensive and (2) the ability of the prescription drug supply chain to increase drug prices faster than general inflation.

How much does the federal government spend on prescription drugs?

The federal government’s share of prescription drug spending has been increasing rapidly. Medicare’s share of total retail prescription drug expenditures climbed from 18% in 2005 (the year Medicare Part D started) to 30% in 2017. By comparison, over that same time period, private insurers’ share of retail prescription drug expenditures (which includes employers) has fallen slight from roughly 45% to 41%.

![Spending on prescription drugs](chart.png)
Why are people seemingly more focused on drug prices?

People are more engaged in the prescription drug pricing debate because it’s easy to relate to the problem. People see the same exact ‘pill’ available from a variety of places at vastly different prices or read about the price of a medication that’s been available for decades being increased by over 5,000%\(^5\). This leaves people with the feeling that there’s no logic or fairness to the way prescription drug prices are set. America’s ‘culture of prescribing’ often positions a medication as a ‘quick fix’ – an easier alternative than making life-style changes to address health conditions.\(^6\)

It’s no secret that the U.S. population is rapidly aging into Medicare. This growing cohort of people are increasingly sensitive to what Medicare Part D will and will not pay for. It’s not uncommon for baby-boomers to see their parents struggling with prescription drug costs, and they don’t want the same situation for themselves. They’re asking questions of policymakers and policymakers are responding.

One recent example is the issue of Medicare Part D’s “doughnut hole”. When Medicare Part D was passed in 2003, the law came with a plan design that made Medicare Part D recipients 100% responsible for the cost of prescription drugs (i.e., the “doughnut hole”). But part of the Affordable Care Act was a provision to eliminate the doughnut hole (closed it) over a 10-year period. Additionally, Medicare Part D prohibited the federal government from negotiating prescription drug prices leaving it to insurance companies to do the heavily lifting in this area. But, many in Congress are looking at the prices paid under Medicare Part D and seeing that they are much higher than what the federal government pays for prescription drugs for programs where it does negotiate drug prices.\(^7\) This has politicians, policymakers, and citizens asking why.

Lastly, through social media, individuals can get instant access to compare data and experiences and pressure politicians. As these issues become increasingly important to a greater number of voters, politicians and policymakers are feeling the need to address them.

Mounting Political Pressure

President Trump has spoken and tweeted regularly on drug prices, and he has already signed legislation aimed at price transparency to bring down prescription drug costs.\(^8\) The Trump Administration continues to propose various regulatory changes aimed at reversing the cost trends on prescription drug prices. For his part, Senator Bernie Sanders (I-VT) has long been a proponent of what is known as drug reimportation. Under current law, drugs manufactured under an FDA-supervised process and that are sold for less outside the U.S. (because the country in which the drug is
dispensed has negotiated better pricing – in some cases, “cents on the dollar” pricing) cannot be ‘re-imported’ into the U.S. Citizens elsewhere receive the benefits (assuming their home country allows the drug’s importation and sale) and typically pay substantially less for the very same FDA-approved and manufactured drug. Legislation to allow re-importation failed by a sizable margin when the Senate considered it in 2017 with 13 Democratic senators voting against the proposal. To date, three states (Vermont, Colorado and Florida) have passed legislation seeking to establish programs to import drugs from Canada.

PRESCRIPTION DRUG PRICES AND THE GREAT POLITICAL DIVIDE

In looking at the approach policymakers are advocating to deal with higher prescription drug prices, the initiatives seem to fall into one of two broad categories: initiatives aimed at influencing prescription drug prices through greater transparency and those aimed at influencing prices through regulations or legislation.

To give a flavor around the concept of transparency, one proposal would require prescription drug prices to be listed in television advertising. Another approach considered over the years by the Department of Labor is the idea of requiring PBMs to disclose the rebates they are paid by drug manufacturers for placement on the PBM’s formulary. The use of formularies was designed to help patients access the prescription drug deemed most effective for their specific diagnosis, but in many ways the use of a PBM’s formulary has become a large bargaining chip in price negotiations between PBMs and drug manufacturers.

HOW A PBM’S FORMULARY AFFECTS PRESCRIPTION DRUG PRICE NEGOTIATIONS

The health benefit programs that most employers offer provide different deductible levels and copays within their prescription drug strategy. It’s very common to ask employees to pay less for a generic drug than they’d pay for a brand-name drug. But, in cases where there are drug manufacturers offering competing brand-name drugs in the same therapeutic class (e.g., high-blood pressure or elevated cholesterol), each manufacturer wants the PBM to lists its product on the PBM’s formulary. Prescription drugs on the PBM’s formulary are typically the preferred ‘brand-name’ drug available to employees with the employer’s health program picking up some or all of the cost. Prescription drugs NOT listed on the PBM’s formulary are still available to
employees, but the employee is typically required to pay a lot more (or possibly the entire cost). So, placement of a prescription drug on the PBM’s formulary is critical to brand-name medication’s sales. Given this ability to ‘steer’ patients, drug manufacturers offer PBMs ‘rebates’ that lower the aggregate price the PBM pays for the drug. Drug manufacturers also offer larger rebates (i.e., a lower overall price) if the PBM agrees to list all of the manufacturer’s prescription drugs on its formulary. The more of the manufacturer’s drugs the PBM agrees to place on its formulary, the higher the rebate percentage the PBM receives. In essence, PBMs have a financial incentive to steer employees to one drug manufacturer’s products, which the PBM often shares with the employer/plan sponsor via more advantageous pricing.

### EFFORTS TO REGULATE ACCESS AND COMPETITION

Given the breath of regulations that already occupy the prescription drug space, most of the legislative and regulatory proposals are aimed at regulating access and increasing competition. This is taking the form of an administration proposal to prohibit drug manufacturer rebates all together. While the proposal appears less than ‘free-market’ in nature, it’s important to realize that very little is truly ‘free-market’ when it comes to the approval, production, distribution and sale of prescription drugs.

Efforts at reimportation are a way to add competition to drug prices. Today, only FDA-approved drugs can be sold in the U.S. Safe and effective drugs are available for much less outside the U.S. (many made in the exact same plants as drugs sold in the U.S.). For example, a drug available through Germany that was used to treat a specific disease state cost $1,900 for a one-year supply. A company purchased the U.S. distribution rights to the medication and the price was increased to $15,000 for a one-year supply. Same medication – no research and development – simply the application of U.S. laws for the exclusive right to distribute the drug and nearly an 8-fold price increase. In 2015, Reuters ran a report that documented that the top 20 drugs sold in the United States were 33% cheaper in Britain. Headlines like that seem common place today. As a result, in October 2018, the Trump Administration asked for comments on whether Medicare should pay for drugs using an international reference pricing scheme. The intent is to make sure that U.S. consumers are not paying more than their counterparts in the rest of the industrialized world.

### WHAT THIS MAY MEAN FOR EMPLOYERS

While few if any of the regulatory and legislative proposals are specifically
geared to impacting employer-sponsored prescription drug coverage, it’s a certainty that employers will need to remain vigilant. If Medicare is able to negotiate prescription drug prices, a potential unintended consequence could be a cost-shift to employer health coverage as manufacturers seek to make up profits lost under Medicare. Additionally, medicine is advancing so rapidly that prescription drug treatments costing more than a $1,000,000 were unthinkable only a few short years ago. It’s a reality today.

Employers can stay engaged by supporting efforts aimed at reducing the barriers to entry for generic and biosimilar drugs. Employers should continue to constantly monitor their prescription drug supply chain contracts looking for opportunities to leverage their buying power. Most large employers have chosen to bundle their prescription drug buying through a PBM. As PBMs work to increase their reach within the health field, there may be opportunities to leverage further PBM capabilities to achieve cost-savings.

SUMMARY

As the U.S. heads into another presidential election cycle, it’s likely that the prescription drug debate will be a hot topic of discussion. With an aging population and increasing budget deficits, Congress and policymakers will have their hands full trying to balance the competing interests influencing the prescription drug pricing debate. It’s likely that only a handful of legislative proposals will actually see a committee vote to advance the legislation out of committee, but some pieces of legislation face strong prospects for enactment. One example is the Creating and Restoring Equal Access to Equivalent Samples (CREATE) Act. The purpose of the CREATE Act is to make it easier for generic drug manufacturers to access name-brand drugs to get FDA approval of their generic drug. Other initiatives seem more destined to be a bullet point in a campaign flyer than legislation likely to be passed by Congress. A bipartisan drug pricing bill is expected to be introduced by the Senate Finance on June 19, 2019.

WHAT’S BEHIND THE CREATE ACT?

For a generic drug manufacturer to get its generic drug approved, it needs to demonstrate to the FDA that its generic drug is the therapeutic equivalent of the brand-name drug. To make that showing, the generic manufacturer needs to have access to the actual brand-name drug in order to run the FDA required tests. A generic drug manufacturer cannot simply call someone and order a bottle of the brand-name drug. The dispensing of prescription drugs is heavily regulated. The medication has to go through a process in order for it to be dispensed to the generic manufacturer for
required FDA-testing. Leveraging this constraint, brand-name drug manufacturers have no incentive to make it easier for generic manufacturers to access to their products in order to conduct their therapeutic equivalent tests. The CREATE Act would remove the hurdles currently in place.
APPENDIX ONE: UNDERSTANDING PRESCRIPTION DRUG PRICING JARGON

The following is intended to be an easy-to-follow reference explaining some of the ‘jargon’ used in the prescription drug pricing debate.

1. **Drug Reimportation:** Many drugs sold in the U.S. are made outside the U.S. in FDA approved factories (many in India). The medications are then shipped across the globe to those countries where their sale has been authorized. The prices countries pay for the same prescription varies greatly. Drug reimportation should NOT be confused with “counterfeit” drugs.

2. **Counterfeit Drugs:** These are prescription drugs that are made in non-FDA approved facilities and are made with the authorization of the company that developed the medication.

3. **Specialty Pharmacy:** There is a growing number of prescription drugs that are ‘tailor-made’ for each patient. The prescription may involve compounding (putting together) different medications. Prescription that are dispensed through a Specialty Pharmacy often require special handling (e.g., refrigeration, or a nurse to administer the medication). There has been a growing concern that more and more prescription drugs (for one reason or another) have been moved out of standard pharmacy distribution channels to higher cost “Specialty Pharmacy” distribution simply for the purpose of increasing the cost of the dispensed drug.

4. **Rebates:** This refers to financial incentives that drug manufacturers will pay to a Pharmacy Benefit Manager (PBM) for listing their ‘named brand’ drug on the PBM’s preferred formulary. PBMs receive rebates because PBMs maintain a drug formulary which spells out which prescription drugs will be ‘preferred’ for a given therapeutic class. As part of setting the level of rebates, it is not uncommon for a drug manufacturer to ‘bundle’ their entire line of products and offer the PBM greater rebates if the PBM includes all the manufacturer’s prescription drugs on its preferred formulary. Unlike PBMs, retailers typically do not receive rebates because drug manufacturers are not convinced that the retailers can sway consumers to purchase their prescription drug over competitor’s.

5. **Formulary:** This is a list of ‘preferred’ medications by therapeutic class that the PBM puts together with the help of its medical professionals. The purpose of the Formulary is to ‘steer’ patients to the most therapeutically effective medications but being listed on a PBM’s formulary often translates to preferred status (less hoops) that a patient must go through in order to obtain the medication.

6. **Couponing:** Given the growing prevalence of high-deductible plans, drug manufacturers have devised couponing programs where the drug manufacturer will cover almost of a patient’s deductible, but once the deductible is met manufacturer coupons no longer work to discount the price of the prescription. This results in employers picking-up the full cost. Medicare Part D members cannot use the same coupons for their medications. Couponing is limited to individuals covered by traditional health insurance.
7. **Brand-name vs. Generic Drug:** Surprisingly, there is no universally recognized definition of what constitutes a ‘brand-name’ drug versus a generic drug. Many PBM contracts include a very specific (highly individualized) definition of what will be treated (for PBM contractual purposes) as a ‘brand-name’ drug versus a ‘generic’ drug. One common example is ‘single-source’ generic drugs. PBMs will typically define ‘brand-name’ drugs to include ‘single-source generic’ drugs under the theory that the PBM has no more negotiating leverage with the manufacturer of a single-source generic drug than it has with the manufacturer of the brand-name drug.

8. **Single-source Generic:** This is a medication manufactured by a third-party after the patent rights have expired on brand-name drug. The term ‘single-source’ means that there is only one generic drug manufacturer making the drug in question.

9. **Pay to Delay:** This is a technique where a brand-name drug manufacturer pays generic drug manufacturers to not produce a generic alternative to the brand-name manufacturer’s product.

10. **Orphan Drug:** This refers to a class of drugs for which there is a prescription that addresses a particular disease state, but for which there are very few individuals with that disease state making production of the drug (and the regulatory hurdles it takes to manufacture the drug) uneconomical to produce the drug. Congress passed an Orphan Drug law in 1983 that gave enhanced patent protections to manufacturer’s classified as “Orphan Drugs.” Several spectacular news stories have been written about extreme price increases related to previously low-cost ‘orphan drugs.’

11. **Exclusivity:** This refers to the 180-day period during which the first company to bring a generic to market must compete. The purpose of the Exclusivity period is to provide companies with an incentive to quickly introduce generic alternatives. The exclusivity period gives the generic manufacturer some short-term market pricing power.

12. **Biosimilar:** This refers to a biologic medical product that is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original "innovator" products and can be manufactured when the original product's patent expires. Biosimilars differ from generic drugs in complexity of the underlying medical product. Biosimilars often replicate very expensive biologic medical products.

13. **Employer Group Waiver Plans (EGWPs, or “Egg Whip” program):** When Medicare Part D was introduced, Congress authorized the Center for Medicare & Medicaid Services to reimburse employers who continued their prescription drug benefits for retired employees. The amount of the subsidy varies, but this program has meant that some employers have continued to offer prescription drug benefits through the employer’s program (vs forcing retirees to seek Medicare Part D coverage).
14. **Medicare Part D “Doughnut Hole”:** Medicare Part D does not cover 100% of the cost of prescription drugs. The Medicare Part D plan design had a gap in coverage where Medicare Part D did not pay anything towards the cost of an individual’s prescription drugs. Thus, Medicare Part D recipients shopped around to find a Medicare Part D supplement that covered their specific medications, so the recipient didn’t fall into the “doughnut hole.” The Affordable Care Account phased out the doughnut hole over a 10-year period. The purpose was to relieve the financial burden higher cost drugs placed on seniors.

15. **Limited Distribution Network:** A limited distribution network (LDN) is used to restrict a prescription drug’s distribution channel to one (or a very small number) of distributors. The strategy is meant to allow for more effective allocation of the drug in the case of shortages and to help ensure the safe distribution of high-risk drugs to small patient populations. However, in recent years, some drug companies, including Turing Pharmaceuticals (the home of “Pharma Bro” CEO Martin Shkreli) used a Limited Distribution Network to prevent generic and biosimilar companies from accessing samples of Turning Pharmaceutical’s drug products so that those generic and biosimilar manufacturers could gain FDA approval of their generic and/or biosimilar drugs.
## APPENDIX TWO: TABLE OF PRESCRIPTION DRUG PRICE INITIATIVES

### Efforts to Increase Price Transparency

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<tr>
<th>Proposal</th>
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<th>Status</th>
<th>Commentary</th>
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<tr>
<td>Regulation requiring TV drug ads to state the drug’s price</td>
<td>Center for Medicare &amp; Medicaid Services</td>
<td>White House Office of Management &amp; Budget reviewing final regulation prior to release (Mar. 20, 2019)</td>
<td>If the regulation becomes effective, it could well generate questions as to why employer drug prices charged are different than shown in advertisements</td>
</tr>
<tr>
<td>Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019 or the ‘‘BLOCKING Act of 2019’’</td>
<td>Introduced in the House by Reps. Kurt Schrader (D-OR) and Buddy Carter (R-GA). No companion bill in the Senate.</td>
<td>Referred to the committee of jurisdiction.</td>
<td>Legislation would discourage the parking or stalling of a company’s use of its 180-day exclusivity by a first generic applicant</td>
</tr>
<tr>
<td>Fair and Immediate Release (FAIR) of Generic Drugs Act</td>
<td>Introduced in the House on March 19, 2019 by Rep. Nanette Barragán (D-CA). No companion bill in the Senate.</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would allow any generic filer who wins a patent court challenge or is not sued for patent infringement by the brand manufacturer to share in the 180-day exclusivity period of first applicants that enter into patent settlements that delay entry.</td>
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## Efforts to Regulate Price through Access/Competition

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<th>Proposal</th>
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<tr>
<td>Regulation prohibiting drugmaker rebates paid to pharmacy benefit managers (PBMs).</td>
<td>Health and Human Services (HHS).</td>
<td>Proposal in initial stage of development (Jan. 31, 2019)</td>
<td>Many employers benefit from drug rebates through their PBM contracts. PBM contracts would need to be renegotiated.</td>
</tr>
<tr>
<td>Legislation to establish two programs: (1) permit Florida to import drugs from Canada for Medicaid and state prisoners; and (2) a separate bill would make importation from Canada available to Florida state residents</td>
<td>State of Florida Legislature</td>
<td>Supported by Florida’s Governor; Legislation has passed several key legislative committees.</td>
<td>Proposal allowing Florida residents to purchase drugs imported from Canada may lower the cost of drugs across the board. It depends on what therapeutic drug classes will be allowed to be imported.</td>
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<tr>
<td>Medicare Negotiation and Competitive Licensing Act</td>
<td>Introduced in both the House and Senate on February 7, 2019 by Congressman Lloyd Doggett (D-TX) and U.S. Senator Sherrod Brown (D-OH)</td>
<td>Referred to the committee of jurisdiction.</td>
<td>Proposal would authorize the HHS Secretary to negotiate drug prices and, if drug companies refuse to negotiate in good faith, enable the Secretary to issue a competitive license to another company to produce the medication as a generic.</td>
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<td>Right Rebate Act of 2019.</td>
<td>Introduced in the Senate on January 24, 2019 by Senator Ron Wyden (D-OR)</td>
<td>Referred to the committee of jurisdiction.</td>
<td>Proposal would close a loophole in Medicaid that has allowed drug manufacturers to misclassify their drugs thereby overcharging taxpayers by billions of dollars and provide HHS with additional authorities to that ensure drugs are properly classified.</td>
</tr>
<tr>
<td>Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act.</td>
<td>Reintroduced in both the House and Senate on February 5, 2019.</td>
<td>Enjoys broad political support but has failed to get traction in the past. Referred to the committee of jurisdiction.</td>
<td>If passed, this legislation would make it easier for a generic drug manufacturer to get access to the name-brand prescription drug in order to prove to the FDA that the generic is the “therapeutic equivalent” of the named-brand drug.</td>
</tr>
<tr>
<td>Preserve Access to Affordable Generics and Biosimilars Act.</td>
<td>Re-introduced on January 9, 2019 in the Senate. Has bipartisan support.</td>
<td>Enjoys bipartisan support but has failed to get traction in the past. Referred to the committee of jurisdiction.</td>
<td>If passed this legislation would prohibit named-brand drug manufacturer’s from paying generic manufacturers to not produce generic equivalents; bill would prohibit pay-for-delay schemes regarding biosimilar drugs</td>
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<tr>
<td>Preserving Access to Cost Effective Drugs (PACED) Act.</td>
<td>Re-introduced in the Senate by Senator Tom Cotton (R-AR), Joni Ernst (R-IA) and Pat Toomey (R-PA)</td>
<td>Referred to the committee of jurisdiction.</td>
<td>Legislation is aimed at restoring the power of the Patent and Trade Office, federal courts, and the International Trade Commission to review patents regardless of sovereign immunity claims made as part of sham transaction. Under current law patent holders can pay Indian tribes to take “ownership” of their patents, which allows the tribes to claim sovereign immunity and avoid review in the case of a dispute.</td>
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<tr>
<td>A Budget for A Better America</td>
<td>Trump Administration Budget submission</td>
<td>Budget sent to Congress for its consideration</td>
<td>Budget proposes strategies targeted at increasing competition, encouraging better negotiation, incentivizing lower list prices, and lowering out-of-pocket costs for Medicare beneficiaries.</td>
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<td>American Patients First Blueprint</td>
<td>May 2018 Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs</td>
<td>Public discussion document.</td>
<td>Trump Administration articulated strategy to deal with drugs prices.</td>
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<td>Biologic Patent Transparency Act</td>
<td>Introduced in the Senate by Susan Collins (R-MA) and Tim Kaine (D-VA); Cosponsored by Portman (R-OH), Shaheen (D-NH), Braun (R-IN) and Stabenow (D-MI)</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would publish and make available to the public a single, easily searchable list (data base) that would include information about various biologics, in addition to explicit information about the patents associated with each product.</td>
</tr>
<tr>
<td>Safe and Affordable Drugs from Canada Act of 2019</td>
<td>Introduced in the Senate on January 9, 2019 by Grassley (R-IA) and Klobuchar (D-MN)</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would permit the importation of prescription drugs from approved pharmacies in Canada.</td>
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<tr>
<td>The Prescription Drug Price Relief Act</td>
<td>Introduced in the Senate and House on January 10, 2019 by Sanders (I-VT) and Reps. Cummings (D-MD) and Ro Khanna (D-CA) and more than 20 democratic co-sponsors</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would peg the price of prescription drugs in the United States to the median price in five major countries: Canada, the United Kingdom, France, Germany and Japan;</td>
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<tr>
<td>The Medicare Drug Price Negotiation Act</td>
<td>Introduced in the Senate and House on January 10, 2019 by Sanders (I-VT) and Reps. Cummings (D-MD) and Ro Khanna (D-CA) and more than 20 democratic co-sponsors</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would direct the Secretary of Health and Human Services (HHS) to negotiate lower prices for prescription drugs under Medicare Part D;</td>
</tr>
<tr>
<td>The Affordable and Safe Prescription Drug Importation Act</td>
<td>Introduced in the Senate and House on January 10, 2019 by Sanders (I-VT) and Reps. Cummings (D-MD) and Ro Khanna (D-CA) and more than 20 democratic co-sponsors</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would allow patients, pharmacists and wholesalers to import safe, affordable medicine from Canada and other major countries.</td>
</tr>
<tr>
<td>A provision in the Massachusetts Governor’s 2020 Budget Proposal</td>
<td>Governor of Massachusetts</td>
<td>Being considered by the Massachusetts State legislature.</td>
<td>The bill would provide authority for MassHealth to negotiate prices directly with the manufacturers of high-cost drugs that have little or no competition and, if that effort fails to produce savings, to put the companies through a rate-setting process followed by regulatory and legal penalties if the firm fails to charge the target price.</td>
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<tr>
<td>The Medicare Negotiation and Competitive Licensing Act</td>
<td>Introduced in the House and Senate on February 7, 2019, by Senators Brown (D-OH) and Baldwin (D-Wis.) and several Democratic House members</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would allow Medicare to negotiate drug prices and strip patent exclusivity from pharmaceutical companies if those negotiations fail.</td>
</tr>
<tr>
<td>The Stop Price Gouging Act</td>
<td>Introduced in the House by Congress members Mark Pocan (D-WI) and Marcy Kaptur (D-OH)</td>
<td>Referred to the committee of jurisdiction.</td>
<td>The bill would require drug makers to report and justify price increases and penalize a company that engages in unjustified price increases with financial penalties proportionate to the price spike.</td>
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ENDNOTES

1 Note that only legislation that was introduced or re-introduced is discussed in this paper. Many bills were introduced in December 2018 at the end of the 115th Congress. Unless passed in the 115th Congress, those bills (by rule) die when the 115th Congress adjourned.


7 The federal government negotiates drug prices on behalf of the VA. CMS is looking to allow letting states negotiate drug prices in their Medicaid programs in certain cases.


10 States must seek and obtain approval from the U.S. Secretary of Health and Human Services (HHS) to implement their laws. “Two More States Seek to Establish Prescription Drug Importation Programs.” Hyman, Phelps & McNamara. http://www.fdalawblog.net/2019/05/two-more-states-seek-to-establish-prescription-drug-importation-programs/
Typically, generic and/or Over-The-Counter (OTC) medications are less costly for both employees and employers than brand-name drugs, but employers should be vigilant to situations where the brand-name drug (after the drug loses patent protection) may, in fact, be less expensive than an OTC or generic alternative.

Employers should be cognizant of PBM rebate arrangements and should ask for an accounting of rebates and their application under the employer’s PBM contract.

