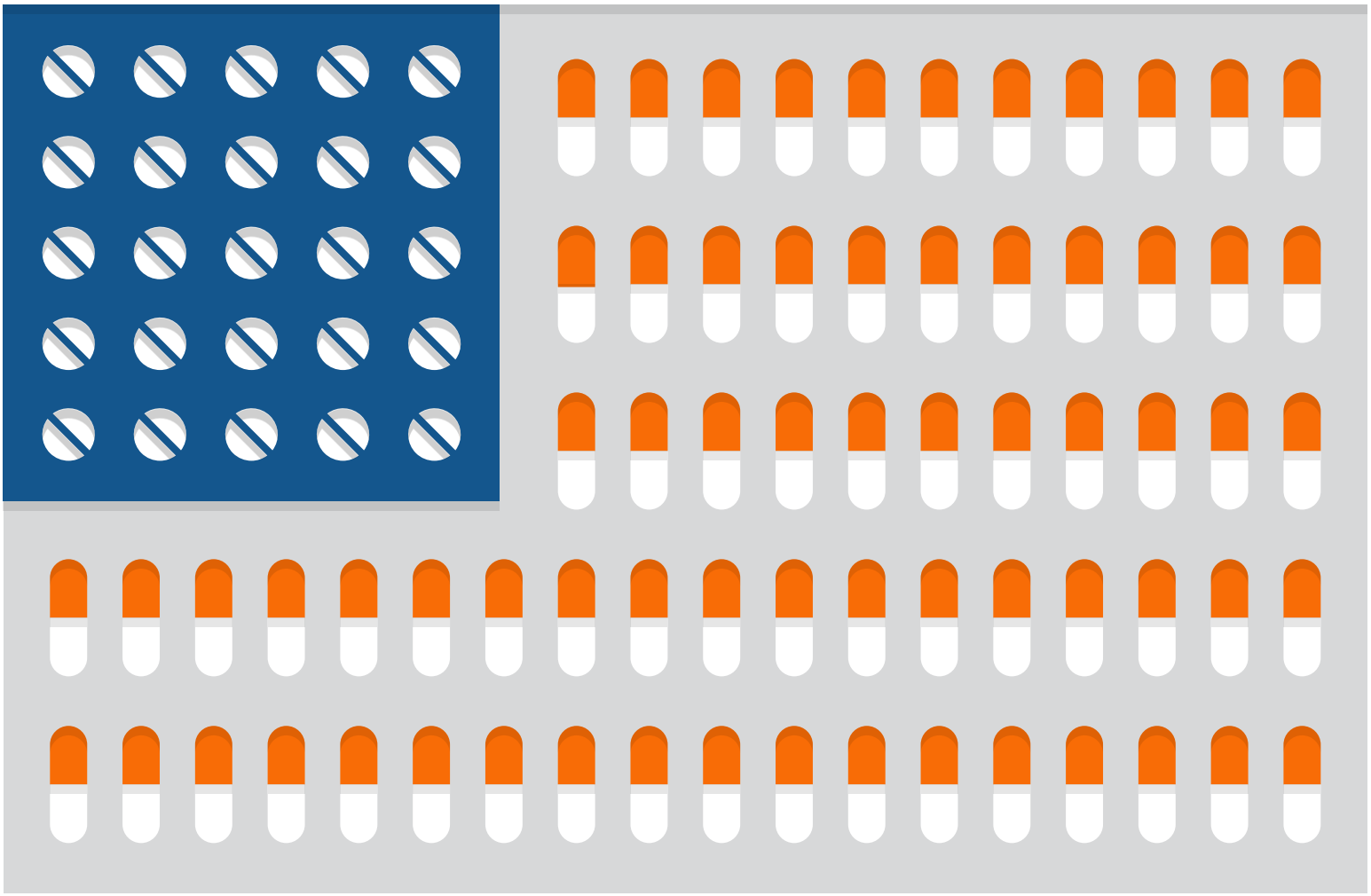


FEBRUARY 2018

Prescription Drug Pricing: A Public Policy Analysis

EXPRESS SCRIPTS®

Prescription Drug Pricing: A Public Policy Analysis

The national debate on prescription drug prices continued throughout 2017. Headlines regularly emerged about six-figure drug launch prices, drug makers using creative methods to avoid competition, and varied appeals for lawmakers to do something about the problem. In the presence of bipartisan outrage, bipartisan policy ideas seemed elusive, despite more than 140 bills filed this Congress that addressed prescription drug pricing.[1]

Even with high drug prices in the public eye, lawmakers have yet to coalesce around legislation to address the issue. President Trump has made his feelings on the subject clear in various speeches, announcements and tweets.

In the aggregate, drug prices remain stable, with spending on prescription drugs increasing only 1.5% in the commercial market last year.[2] For policy makers, deviations across public programs – where health insurance exchanges had drug spending decline 3.3% and Medicaid plans had a 3.7% increase[3] – tell different stories and provide a useful roadmap for which public policies are working better than others.

These aggregate data, however, don't directly reflect or affect the anecdotal patient experience at a pharmacy counter when out-of-pocket costs have doubled. Even though the average patient copay increased only 12¢ for a 30-day supply of medication[4], the outlier experience of a patient with a $1,000 or higher copay is driving the debate.

In February 2017, Express Scripts outlined 15 public policy ideas for lawmakers that remain viable, cost-saving options for public and private payers. These policy ideas addressed five marketplace behaviors, which persisted all year:

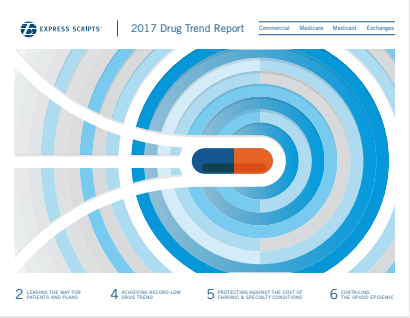
1. **Hyperinflation among brand biologics and insulins**
2. **High introductory prices for novel drugs**
3. **Hyperinflation among single-source drugs**
4. **High prices with abusive product combinations**
5. **Hyperinflation following public policy support for medicines**

Proponents of these policy recommendations are making progress and passage of some policies appears certain in 2018:

- Lawmakers are seriously considering reforms to prevent abuse of Risk Evaluation and Mitigation Strategy (REMS) to delay generic and biosimilar drug launches.
- Food and Drug Administration (FDA) Commissioner Gottlieb has begun to implement a new agenda for the agency that will hasten the launch of brand, generic and biosimilar drugs.
- Expedited generic drug reviews for single-source drugs were already enacted as part of FDARA, the Food and Drug Administration Reauthorization Act of 2017.
- The Centers for Medicare & Medicaid Services (CMS) has proposed allowing Medicare plans to make mid-year formulary changes when new generic drugs launch.

Express Scripts reminds of and reiterates our recommendations from last year's report. At the same time, we note three areas of policy focus that we expound on and suggest are ripe for legislative and/or regulatory attention:

1. **Pay-for-delay patent settlements between biologic and biosimilar manufacturers**
2. **New safe harbors to encourage value-based reimbursement**
3. **Addressing the nation's opioid crisis via e-prescribing, controlled substance limits and monitoring programs**



Gain more prescription drug data and insights in the Express Scripts 2017 Drug Trend Report.

Pay-for-delay settlements between biologic and biosimilar manufacturers

Pay-for-delay agreements hinder the introduction of generics, denying patients access to lower-cost treatments.

Regulators and lawmakers have long paid attention to settlements between brand and generic drugmakers that end patent dispute litigation. In most cases, these settlements provide a specific date that a competing drug could come to market. But in some cases, these settlements also included a payment to the competing manufacturer, giving rise to concerns about an anticompetitive effect. Sometimes, these pay-for-delay agreements have hindered the introduction of generics onto the market, denying patient access to lower-cost treatments.

When Congress enacted the Medicare Modernization Act (MMA) of 2003, lawmakers included legislation that required brand and generic drugmakers to file patent settlement agreements with the Federal Trade Commission (FTC) and the Department of Justice (DOJ). With the information from these settlement agreements, the FTC could evaluate and decide whether to take any legal action to challenge the settlement. This requirement eventually led to the Supreme Court weighing in on the subject in the 2013 case of *Federal Trade Commission (FTC) v. Actavis*.[5] The decision in that case increased FTC scrutiny of pay-for-delay agreements and the agency's ability to challenge them in federal court.

Prescription drugs in 2003, however, were mostly that – drugs. The legislation that required the disclosure of these settlements covered the vast majority of the market in 2003, but does not include biologics or biosimilars. Drugmakers can enter into settlements delaying the market introduction of biosimilars without disclosing said settlement to the FTC.

In one of the most underreported healthcare stories of 2017, a biosimilar settlement between Abbvie, the manufacturer of Humira®, and Amgen, the manufacturer of an FDA-approved biosimilar for Humira, occurred in September. The settlement paid to the potential competitor to the world's top-selling prescription drug (with 2017 global sales of $18 billion[6]) remains confidential, so only some details are available. The companies acknowledge, however, that Amgen can begin selling a biosimilar to Europeans later in 2018, but the same FDA-approved drug will not be available in the United States until 2023.[7]

Congress struck a balance in 2003 by allowing these types of settlements to occur, but requiring oversight by the FTC and DOJ to avoid anticompetitive harms. The same policy needs to be adopted and applied to biologics and biosimilars approved under the Public Health Service Act. Payers' drug spending costs increased minimally in the markets where this oversight exists, but surged more than 11.3% among specialty drugs, including biologics. The best way to reverse this trend is to adopt policies that promote a competitive biosimilars market, which includes ensuring that drugmakers aren't delaying competition themselves.[8] Requiring patent settlements between biologic and biosimilar manufacturers to be reported to FTC and DOJ will ensure that these agencies have the information needed to challenge anticompetitive agreements in federal court.

New safe harbors to encourage value-based reimbursement

Appropriate regulatory flexibility could help drive down costs for Medicare, Medicaid and health insurance exchange plans that want to share risk in novel contracting arrangements.

Pharmacy, like other healthcare sectors, has begun to shift from paying for units to paying for quality. Requiring/applying value from prescription drugs in negotiations with drugmakers can be a difficult task, but Express Scripts has successfully launched programs that reimburse plan sponsors for patient nonadherence, cap inflation costs, vary prices based on indication and set treatment costs for therapy classes.

These new programs, however, are off-limits to public payers (Medicare, Medicaid, exchanges) due to concerns about Anti-Kickback Statute enforcement and the Medicaid best price requirements. To be clear, Express Scripts supports the spirit of these laws in deterring, preventing and punishing bad actors committing fraud or abusing healthcare resources.

Unfortunately, these statutes are inflexible when plans want to share risk in novel contracting arrangements. With the appropriate regulatory flexibility, drugmakers appear willing to expand these programs to additional plan sponsors who are otherwise bound by statutory constraints.

Express Scripts supports efforts, in conjunction with some drugmakers, to propose a new regulatory safe harbor to HHS that allows value-based programs that promote therapy adherence. The precise drafting of such a safe harbor is complex, but critical to moving public programs along with the commercial market in adopting best practices to make prescription drugs affordable.

Addressing the nation's opioid crisis

Two million Americans remain addicted to opioids, and emergency departments treat 1,000 patients a day for misusing these drugs.

No public health issue was more immensely discussed in 2017 than the county's opioid addiction crisis. The President declared a state of emergency; a Presidential panel was convened to develop policy recommendations; Congress convened more than a dozen hearings. Yet two million Americans remain addicted to opioids[9], and emergency departments across the country treat 1,000 patients a day for misusing opioids[10].

The focus of policymaker attention has been varied. Some want to study causes, others want to cast blame, and still others remain concerned about pushback from various stakeholders. We can't blame our way to solving the country's opioid crisis, so Express Scripts spent time doing something about it.

After a yearlong pilot, we introduced our Advanced Opioid Management℠ suite of tools and the program's results speak for themselves. We observed a reduction of nearly 60% in the average days' supply for patients who were prescribed an opioid for the first time.[12] Nearly 96% of those patients started with a 7-day or less supply.

We want federal and state lawmakers to follow suit.

- Require e-prescribing (e-Rx) for controlled substances: E-prescribing has been shown to dramatically reduce medication errors and fraud; yet, until 2010, the Drug Enforcement Agency barred its use for controlled substances. An increasing number of states now require its use. E-prescribing controlled substances would restrict pharmacy shopping, enable better prescription tracking, and reduce fraud. H.R. 3528, the Every Prescription Conveyed Securely (EPCS) Act would move Medicare to a system of e-prescribing for opioids, and would go a long way to saving lives and stopping addiction by eliminating fraudulent paper claims.
- Seven-day opioid prescription limits for acute pain: To prevent patients from getting addicted to pain medication, prescriptions for acute pain should be limited to a 7-day supply. In addition to plan, PBM and payer efforts, we support updating state laws to make this uniform. There are bills in the Senate and House, including S. 892, H.R. 3964, and H.R. 4408 that would amend the Controlled Substances Act to limit first-fill opioid prescriptions to 7 days, with certain exceptions.
- Improve and integrate prescription drug monitoring programs (PDMPs) and require prescribers to check PDMPs: Governments should make their PDMP databases more accessible, more user-friendly, and better integrated across the country – and make the data accurate in real time. The goal would be to create prescriber, pharmacist and insurer access to real-time data. Senators Amy Klobuchar (D-MN) and Rob Portman (R-OH) have introduced legislation mandating the creation and use of strict prescription drug monitoring programs by states that receive federal funding to fight opioid abuse. The Prescription Drug Monitoring Act (S. 778/ H.R. 1854) would require states to compel pharmacies to submit data within 24 hours of filling a prescription. Providers would have to check the PDMP before each prescription of the drugs, and PDMPs would have to notify providers when patients showed worrisome opioid prescription patterns.[13]

Although healthcare is complex, our mission is simple – put medicine within reach of payers and patients. We regularly meet with lawmakers at the federal and state levels to advocate for policies, like the ones reviewed in this report, to deliver on our mission. We believe prescription drug affordability for all is an issue ripe for bipartisanship in 2018. We are encouraged by some of the progress made in 2017, but there is so much more that can and should be done.

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