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# PRESCRIPTION DRUG PRICING: A PUBLIC POLICY ANALYSIS




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# Prescription drug pricing: A public policy analysis

The November 2018 elections provided a glimpse of the power that health care – and in particular, drug pricing – issues had on the American electorate. In a September survey by the West Health Institute and NORC at the University of Chicago, 39% of senior citizen voters answered that prescription drug prices should be the single top priority for candidates.[1] Recent data from AARP showed a similar sentiment from voters over 50, with 92% of them saying the candidates' positions on lowering prescription drug costs were important to them. [2]

During the 116th Congress, drug pricing will remain a major focus as President Trump and numerous members of Congress, including many freshmen legislators, have made the issue a top priority.

Despite the partisanship and political rhetoric around health care, Express Scripts has found legislative success championing our solutions detailed in last year's Public Policy Analysis.[3] Already signed into law are:

- Directives for use of electronic prior authorization capabilities in Medicare[4]
- Mandates for electronic prescribing for controlled substances in Medicare[5]
- Prohibitions on so-called "pharmacy gag clauses."[6]
- Requirements that pharmaceutical companies disclose patent settlements involving biosimilar drugs to the Federal Trade Commission (FTC).[7]

The Express Scripts 2018 Drug Trend Report shows the ongoing success that utilization management and other cost containment tools have on reducing drug spend while maintaining patient access to care. In 2018, U.S. drug spending increased only 0.4% for Express Scripts commercial plans – the lowest trend in 25 years – with similarly low trends in our Medicare and health insurance exchange markets. Public policy must foster wider use of these proven tools that hold down costs for plan sponsors and patients.

**To continue on this path of success we are calling on the President and Congress to take action on the following policy ideas as a top priority:**

1. **Address the misuse of Risk Evaluation and Mitigation Strategies (REMS) by passing and signing the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act**
2. **Support legislation to prohibit "pay-for-delay" arrangements**
3. **Foster the use of e-prescribing for controlled substances in Medicaid and other public programs**
4. **Unleash the potential of value-based benefit designs**


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# Address the misuse of REMS by passing and signing the CREATES Act

The U.S. Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies (REMS) program provides important protections for patient safety by ensuring that the benefits of a drug or biological product outweigh its risks. However, certain brand manufacturers have exploited a loophole in the strategy to prevent generic and biosimilar competition for products with and without REMS requirements.

These manufacturers employ restricted distribution networks to deny prospective generic and biosimilar drugmakers access to the product samples needed to obtain FDA approval. In fact, some brand manufacturers have implemented restricted distribution programs solely to delay competition, independently from any FDA requirements.

The FTC has cautioned that "… this conduct may prevent the Hatch-Waxman framework from functioning as Congress intended."[8] The CREATES Act[9] would block these anticompetitive practices by closing the loophole and establishing a clear pathway for generic and biosimilar manufacturers to access the product samples needed to bring lower-cost traditional and biologic drugs to the U.S. market. **The increased generic and biosimilar competition that would be provided by the legislation is projected to save the federal government $3.9 billion over 10 years.**[10]

Express Scripts joined more than 80 other health care stakeholders[11] in endorsing the CREATES Act. Although the Senate Judiciary Committee approved the measure on a bipartisan vote of 16 to 5 in June 2018,[12] it did not progress any further. Enacting this important measure into law will mark a huge victory for patients seeking lower-cost generic drugs and biosimilars.

**MORE GENERIC AND BIOSIMILAR COMPETITION WOULD SAVE THE FEDERAL GOVERNMENT BILLIONS OF DOLLARS**

# Support legislation to prohibit "pay-for-delay" arrangements

Often, brand and generic drugmakers enter into agreements that delay the market launch of a generic drug in exchange for financial compensation from the brand company to the generic manufacturer. In recent years, as part of increased Federal Trade Commission (FTC) enforcement activity to uncover anticompetitive effects, so-called "pay-for-delay" arrangements have been a main focus.

In our 2018 Public Policy Analysis, Express Scripts identified an increasing number of patent settlements between biologic and biosimilar manufacturers as a trend that lawmakers need to resolve. Brand and generic drugmakers have been required since 2003 to file patent settlement agreements with the FTC, which evaluates the information and decides whether to take any legal action challenging the settlement. That requirement previously did not extend to biosimilar settlements, potentially delaying the market introduction of these lower cost biological treatments.

**A NEW LAW WOULD BRING LOWER-COST GENERICS AND BIOSIMILARS ONTO THE MARKET SOONER**

Fortunately, lawmakers who recognized the need for additional scrutiny of settlements introduced the Biosimilars Competition Act of 2018, which requires biologic and biosimilar manufacturers to report biosimilar patent litigation settlements to federal antitrust regulators.[13] Express Scripts joined a wide range of health care stakeholders in endorsing the legislation.[14] **When the bill was enacted into law in October 2018, it marked a major victory for patients in America.**[15]

In January 2019, Senators Amy Klobuchar (D-MN) and Chuck Grassley (R-IA) introduced the Preserve Access to Affordable Generics and Biosimilars Act.[16] It contains language from previous versions that prohibits anticompetitive agreements between brand and generic drugmakers. Importantly, the new legislation also targets settlements between biologic and biosimilar manufacturers. If signed into law, the measure will save the federal government billions of dollars by curbing anticompetitive agreements and bringing lower-cost generics and biosimilars onto the U.S. market sooner.

Spending on biologic drugs in the U.S. totaled more than $120.1 billion in 2017,[17] with approximately two-thirds of drug spending in Medicare Part B on biologic drugs.[18] With an expected cost discount of 15% to 40% less than originator products,[19] biosimilars create a significant savings opportunity across the U.S. health care system. Enhancing their uptake by preventing anticompetitive settlements between biosimilar and biologic manufacturers is vital to reducing prescription drug costs for American families by bringing biosimilars to market as soon as possible.

# Foster the use of e-prescribing for controlled substances in Medicaid and other public programs

**E-PRESCRIBING CAN SAVE LIVES BY DRAMATICALLY REDUCING MEDICATION ERRORS AND FRAUD**

No public health issue has been discussed more actively over the past few years than the country's opioid addiction crisis. The President declared a state of emergency; a Presidential panel was convened to develop policy recommendations; Congress held more than a dozen hearings; and the SUPPORT for Patients and Communities Act, bipartisan legislation containing many provisions to address treatment and addiction, was signed into law. Yet, 11.4 million American adults and adolescents reported misusing opioids in 2017.[20] In 2016, 66.4% of the 63,632 drug overdose deaths were due to opioid misuse.[21]

The focus of policymakers' attention has been varied. Some study causes, others cast blame and still others fear pushback from various stakeholders. Express Scripts is taking positive steps to help solve it.

After a year-long pilot, we introduced our Advanced Opioid Management[SM] program and the results were dramatic.[22] **The average days' supply for patients being prescribed an opioid for the first time was reduced 55%, from 18.3 to 8.2 days. Better yet, 93% of those patients started with a seven-day supply or less.**

We urge federal and state lawmakers not only to follow our example, but to go even further by enacting the following policies:

### Require e-prescribing for controlled substances

Electronic prescribing has been shown to dramatically reduce medication errors and fraud. Until 2010, though, the Drug Enforcement Agency (DEA) barred its use for controlled substances. An increasing number of states now require its use. E-prescribing for controlled substances restrict pharmacy shopping, enable better prescription tracking and reduce fraud. With the backing of Express Scripts and as part of the SUPPORT for Patients and Communities Act[23], Congress enacted the Every Prescription Conveyed Securely (EPCS) Act, which will move Medicare to a system of e-prescribing for opioids and contribute towards saving lives and stopping addiction by eliminating fraudulent paper prescription claims. Successful implementation of the EPCS Act should inspire Congress to explore similar policies in other federal programs, such as Medicaid.

**FIRST-FILL LIMITS AND MANDATORY MONITORING COULD HELP FIGHT OPIOID MISUSE**

### Limit first-time opioid prescription for acute pain to seven days

To prevent patients from becoming addicted to pain medication, prescriptions for acute pain should be limited to a seven-day supply. In addition to plan, pharmacy benefit manager (PBM) and payer efforts, we support updating state laws to make them uniform. Bills introduced in both the Senate and the House, including the Opioid Addiction and Prevention Act[24], would amend the Controlled Substances Act to limit first-fill opioid prescriptions to seven days, with certain exceptions.

### Improve and integrate prescription drug monitoring programs (PDMPs) and require prescribers to check them

State governments should make their PDMP databases accessible to health care stakeholders, not just to law enforcement and researchers. Additionally, the data should be more user-friendly, interoperable across the country and available in real time. Legislation should mandate the creation and use of strict PDMPs by states that receive federal funding to fight opioid misuse and to grant prescribers, pharmacists and insurers access to PDMP data. Legislation, such as the Prescription Drug Monitoring Act[25], which was introduced in the House and Senate in the 115th Congress, would require states to compel pharmacies to submit data within 24 hours of filling an opioid 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.

# Unleash the potential of value-based benefit designs

**REGULATORY CHANGES CAN ENABLE PUBLIC PROGRAM ENROLLEES TO BENEFIT FROM THE BEST PRACTICES OF COMMERCIAL PLANS**

The rising cost of prescription drugs is a concern for all Americans. Pharmacy, like other health care sectors, has begun to shift from reimbursing per units dispensed to paying for quality. Express Scripts uses novel solutions to keep our clients' drug trend consistently low. Extracting value from drugmakers via negotiations on prescription drug prices can be a difficult task, but we 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.

PBMs, which implement a multitude of tools to manage drug benefits, are well-positioned to support value-based care using real-time medical and pharmacy data. **Medicare and other publicly funded health insurance programs can improve the sustainability of such plans and ensure consumers have affordable access to high-quality care by leveraging the best practices of PBMs.**

However, many new programs are off limits to public payers (Medicare, Medicaid and exchanges) due to concerns about Anti-Kickback Statute enforcement and Medicaid best-price requirements. Express Scripts completely supports the spirit of these laws in deterring and punishing bad actors who commit fraud or who abuse health care resources. Unfortunately, the same statutes also prohibit plans from sharing risk through novel contracting arrangements. Drugmakers appear willing to expand these programs to additional plan sponsors who otherwise are bound by statutory constraints, if flexibility can be introduced into the regulations.

In conjunction with selected drugmakers, Express Scripts supports proposals to the Department of Health and Human Services (HHS) for a new regulatory safe harbor that allows value-based programs promoting therapy adherence. The precise drafting of such a safe harbor is complex, but exact language is critical to aligning public programs more with the commercial market in adopting best practices to make prescription drugs more affordable. Without the regulatory changes necessary to foster such innovative plan designs as those taking hold on the commercial side, public-program enrollees will not benefit fully from value-based or outcomes-based reimbursement models.

Pilot demonstration programs that Express Scripts is exploring in our Medicare prescription drug plans (PDP), could have positive impacts on value and spending for both individual beneficiaries and the entire Medicare program. They include:

- Providing member-focused incentives to promote medication adherence and health goals, such as achieving target blood sugar levels or controlling blood pressure.
- Introducing drug manufacturer financial risk for lack of promised clinical performance when documented adherence is documented. Similarly, offering rewards for reduced health service utilization – fewer ER visits, for example.
- Testing physician risk models that include drug utilization performance measures.

We remain eager to engage the Administration and Congress in discussions to develop these ideas and others, and we welcome all opportunities to do so.

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