Prescription Drug Transparency Reform: While You Wait
In the ongoing quest to harness escalating prescription drug costs, drug price transparency has taken center stage in the fight for reform. Transparency proponents believe reform would not only expose inequities in the drug pricing pipeline, but also create a stronger element of competition that could drive down prices. The goal is to reduce out-of-pocket expenditures for patients by giving them access to cost data with the ultimate goal to of making drugs more affordable.

In a win-win, general healthcare costs would be reduced, as more patients could afford the medications they need, making it less likely their conditions will worsen, sending them back for physician office visits, to emergency rooms or potentially causing them to be admitted for extended stays.

When in doubt of a solution, it is not unusual for the parties involved to look for someone to blame. In the case of drug pricing, the line-up of usual suspects rightly or wrongly includes pharmaceutical companies, pharmacy benefit managers, providers, payers, pharmacy chains, legislatures and regulators.

It is argued, drug price transparency would also help other segments of the healthcare industry. For instance, pharmacies faced with cost reimbursement pressure would have insight to factors that could improve their bottom line performance and would be better informed when negotiating contracts. Drug manufacturers would have a better view of market conditions that could impact their ability to forecast and budget appropriately.

While the goals of pricing reform are clear, the road to a workable solution is not. Drug pricing is an extremely complicated process, with multiple players and conflicting priorities to consider. Due to these industry complexities, there is no formal reform in place today. This has left industry stakeholders looking for ways to address the issue and fill their information gaps in order to better assist consumers with compliance.

Eight in 10 Americans perceive prescription drug costs as “unreasonable.” More than 80 percent say government is “not doing enough” to remedy this situation.1
States Take the Lead

Under pressure from their constituents and their financial responsibilities under Medicaid, exacerbated by balanced budget mandates, state governments increasingly have taken the helm in drug price reform. In the 2018 legislative sessions alone, 28 states passed 45 laws pertaining to the cost, pricing and payment for pharmaceuticals.ii

During last year’s unprecedented flurry of action to curb drug costs, seven states enacted new drug price transparency laws, 20 states addressed “objectionable PBM practices” and Vermont passed a measure enabling the state to pursue federal certification for a wholesale importation program from Canada.iii

Connecticut, beginning in January 2020, will require drug manufacturers to provide information on significant drug cost increases, including factors that triggered the hike, and information about drug development costs and capital expenditures. In addition, payers will be required to submit data about their most frequently prescribed and highest-cost drugs, as well as the impact of drug costs on the plan and its members, and PBMs must report the volume of formulary rebates received from drug makers, including the portion provided to health insurers.iv

At least eight states have passed laws that aim to expose questionable medication pricing and compel drug makers to provide the reasoning behind their cost decisions.v

Starting in 2019 in Colorado, healthcare cost reporting requirements were expanded to mandate that insurers submit to the Commissioner of Insurance information regarding prescription drugs covered under their plans that were dispensed in the preceding year. Also in Colorado, prescription drug manufacturers, on or after July 1, 2018, were required to notify state purchasers, insurers and PBMs when the manufacturer increases the price of certain prescription drugs by more than 10 percent or introduces a new specialty drug into the commercial market. Separate legislation requires drug manufacturers to submit reports to the State Board of Health for diabetes products when the price increases relative to the increase in the medical component of the consumer price index. There are financial penalties for failure to comply.vi

States also are taking administrative action as well to better manage their spending on Medicaid pharmacy benefits.

Notably, Ohio’s Medicaid Department – reacting to analyses showing that the two largest PBMs in the state billed its managed-care plans (MCOs) $223.7 million more for prescription drugs than they reimbursed pharmacy providers in one year under a practice known as “spread pricing” – has directed the MCOs to end their contracts with PBMs that use that mechanism and strike up new ones with companies able to manage pharmacy services using a more transparent pricing model.vii

In addition, the Ohio Department of Insurance in April 2018 issued a bulletin barring health insurers and PBMs from charging consumers more for their prescription drugs than what it would otherwise cost without insurance coverage, and banning “gag orders” that can forbid pharmacists from letting customers know of lower-cost alternatives.viii

Within months, the gag order ban was replicated on the Federal level, as President Donald Trump signed the Know the Lowest Price and Patient Right to Know Drug Prices Acts, and the Centers for Medicare & Medicaid Services (CMS) joined the fray.
Gag Order Ban

About half of U.S. states have enacted bills banning gag clauses on prescription drugs. Florida joined that group in July 2018, passing drug transparency legislation freeing pharmacists to tell customers whether the cost-sharing obligations exceed the retail price of their prescriptions and requiring them to inform customers about the availability of less expensive generically equivalent drugs.

CMS Weighs In

Proposal to put prices in TV ads

In October 2018, CMS announced a proposed rule to require prescription drug manufacturers to post the wholesale acquisition cost (WAC) for drugs covered by Medicare or Medicaid in direct-to-consumer television ads. The price required to be posted would be for a typical course of treatment for an acute medication, such as an antibiotic, or a 30-day supply of medication for a chronic condition that is taken every month, and the posting would take the form of a legible textual statement at the end of the ad. An exception was made for drugs with list prices of less than $35 per month.

While America’s Health Insurance Plans (AHIP) expressed approval of the announced rule, the Pharmaceutical Researchers and Manufacturers of America, (PhRMA) immediately went on record stating that putting list prices in isolation in the ads would be misleading or confusing, perhaps leading to non-adherence of medications, and promising that pharmaceutical companies would direct consumers to websites that include a drug’s list price and estimates of what they can expect to pay, which can vary widely depending on coverage. It also argued that disclosing the price in ads would not benefit patients because they aren’t what a consumer would pay at a pharmacy. The association did not rule out legal action should the rule be put in place, citing substantial statutory and constitutional principles, including First Amendment concerns.

A significant downside, critics added, is that the proposed rule has no government enforcement mechanism, instead depending on “shaming” via listing of companies violating the mandate and leaving it to the private sector to police itself with litigation.

New and Proposed Policies

Earlier in 2018, and mimicking state action, CMS notified companies that provide Medicare prescription drug coverage in Part D that gag clauses are unacceptable under Administration-wide efforts to lower prescription drug costs.

In related action, CMS also proposed a series of policy changes, including adoption of a new pricing model for Medicare Part B drugs aimed at ensuring the prices patients pay for prescriptions accurately reflect the true cost and cutting the WAC-based reimbursement of Part B drugs from 6 to 3 percent.
The Administration Takes Aim

In May 2018, the Trump Administration published “American Patients First,” its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs designed to target what the U.S. Department of Health and Human Services identified as the key challenges in the American drug market:

- High list prices for drugs
- Seniors and government programs overpaying for drugs due to the inability of government to negotiate the price of drugs
- Rising out-of-pocket costs for consumers
- Foreign governments free-riding off American investment in innovation

In the document, the Administration presented several proposals to increase competition in the prescription drug market, including expanding the availability of biosimilars, increasing value-based reimbursement in Medicaid and Medicare, and adding transparency and cost negotiation tools for drugs purchased and paid for through Medicare Part D.

In efforts to reform Medicare Part B and 340B programs, proposals also were made to add limits to Medicare Part B drug price increases and create prescribing-based financial incentives for providers.

While payers and associated trade groups expressed overall enthusiasm about the proposed reforms, some explicitly expressed concerns on the proposals relating to rebates, an ongoing hot-button issue. Among comments, AHIP told the press: “Insurance providers share the savings from negotiations with drug manufacturers by lowering premiums and copays for all consumers. . . . Requiring drug rebates to be passed through to Medicare patients at the pharmacy counter would likely lead to higher drug prices from manufacturers, and would lead to higher premiums for seniors, as well as $40 billion in additional costs for hardworking taxpayers.”

Some experts also disagree with the proposed policy to switch some Medicare Part B drugs to Part D. Critics feel this policy could result in unintended patient access barriers caused by differences in payment, cost sharing, reimbursement and settings of care. Under Part B, providers administer the drug and submit a claim for reimbursement that covers both the medication and its administration, while standalone prescription drug plans in the Part D program usually contract with pharmacies to make the medications available directly to consumers. This payment divide, they contend, could spell trouble for hospital providers who may have to administer Part D-covered drugs.
The proposed shift of Part B drugs under Part D would likely present a significant change for providers in terms of revenue and their role in purchasing, storing and billing for physician-administered drugs.

Going Forward

The public outrage regarding high prescription drug prices will continue, given the healthcare movement toward engaging patients more in their care and ongoing price increases. That said, significant Federal legislative or regulatory action is expected in 2019, some experts say.¹⁰

In late February 2019, pharmaceutical executives testified before the Senate Finance Committee in one of a series of planned drug-cost hearings, highlighting drug rebates as a contributing factor to higher drug prices and endorsing an overhaul to the rebate system. Other stakeholders, when they get their turn, no doubt will have additional – and different – issues they believe should be addressed.

And, despite legislators’ urging and wishes, there will be no quick fix.

A lot of the blame can be placed on the sheer complexity of the issue, complicated by those widely differing opinions of what can and should be done. Even with expected regulatory action, drug pricing reform will not be immediate and will continue to be top of mind as the industry moves forward.

Elsevier Drug Pricing Solutions

Elsevier is the industry leader for the most current, accurate and reliable drug pricing information. Elsevier’s drug pricing begins with data reported directly from pharmaceutical manufacturers, published the same day it is received or on the effective date through TRUE Daily Updates™. Our drug pricing is available via flexible solutions to fit the needs of users across the healthcare spectrum. Among them are:

• **ProspectoRx**, the industry’s most powerful, web-based and only real-time drug pricing and analysis tool, which delivers immediate access to price changes as soon as they are effective.

• **Gold Standard Drug Database Pricing Module**, the only drug database solution providing immediate, accurate and advanced price data for seamless integration into health systems/applications.

• **Predictive Acquisition Cost**, which utilizes predictive analytics to deliver the most reliable and current acquisition-based drug price solution for drug price transparency, price setting, cost containment and insightful analysis.

With these solutions, Elsevier helps pharmacy, payers/PBMs, pharmaceutical manufacturers and wholesalers/distributors to remain informed and competitive in today’s complex drug landscape.
For more information, please visit Elsevier.com/drug-information