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PRICE TRANSPARENCY IS COMING

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What's Next in the March to Price Transparency?

HERE'S WHAT YOU NEED TO KNOW TO GET READY

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PRICE TRANSPARENCY IS COMING

Here's what you need to know to get ready

PRICE TRANSPARENCY EBOOK

Price transparency has been top of mind for medtech and pharmaceutical manufacturers for many years. In 2019, a proposed rule to eliminate drug rebates in certain Medicare and Medicaid plans seemed inevitable—until it was abruptly cancelled – and several other proposals have been debated.

Now, the Prescription Drug Price Reduction Act, or PDPRA, has taken center stage as it makes its way through the legislative process. PDPRA advanced through the Senate Finance Committee on July 25, 2019, and is now being considered by the full Senate.

While waiting for the legislative process surrounding PDPRA to play out—with uncertainty on precisely what will happen and when—those in the industry are once again left to wonder what the impact of this legislation might be and what firms should be doing to prepare.

The Big Idea

Controlling drug costs and increasing price transparency remain political priorities. The rising cost of healthcare is in the news every day, with much of the blame, rightly or wrongly, being placed on drug pricing. Therefore, even though pharmaceutical manufacturers are uncertain about the specifics and timing of PDPRA and other future regulations and legislation, it is certain that price transparency will remain in the spotlight as a focal issue for consumers and regulators. Therefore, even though pharmaceutical manufacturers are uncertain about the specifics and timing of PDPRA and other future regulations and legislation, it is certain that price transparency will remain in the spotlight.

Sitting back and doing nothing is not a prudent option. Instead, manufacturers can use this time wisely to prepare for greater price transparency. This includes building agility into contracting, pricing, and sales environments. It entails reviewing all software to ensure you are using the most recent versions and considering the cloud as a tool to assist with upgrades and managing compliance. It also means continuing the ongoing quest toward digital transformation. By taking these steps, pharma manufacturers will be well prepared to thrive regardless of what comes next.

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How did we get here?

Spending on drugs constitutes only 10-15% of total healthcare spending

But the fervor about drug costs seems to dominate 100% of political discussions and news headlines about healthcare.

Amid unprecedented political dissension, the political parties do seem to agree on one thing: **that U.S. drug prices are way too high and need to be reined in.** Attacking drug companies and drug prices has become a political rallying cry for politicians of all stripes, even though many politicians lack a clear understanding of how drug pricing works. Despite the fact that spending on drugs constitutes only 10-15% of total healthcare spending, the fervor about drug costs seems to dominate 100% of political discussions and news headlines about healthcare. Aside from the occasional story about a bloated emergency room bill, it is rare to see any mention of surgery costs, labor or hospital overhead costs. Politicians seem fixated on drug prices.

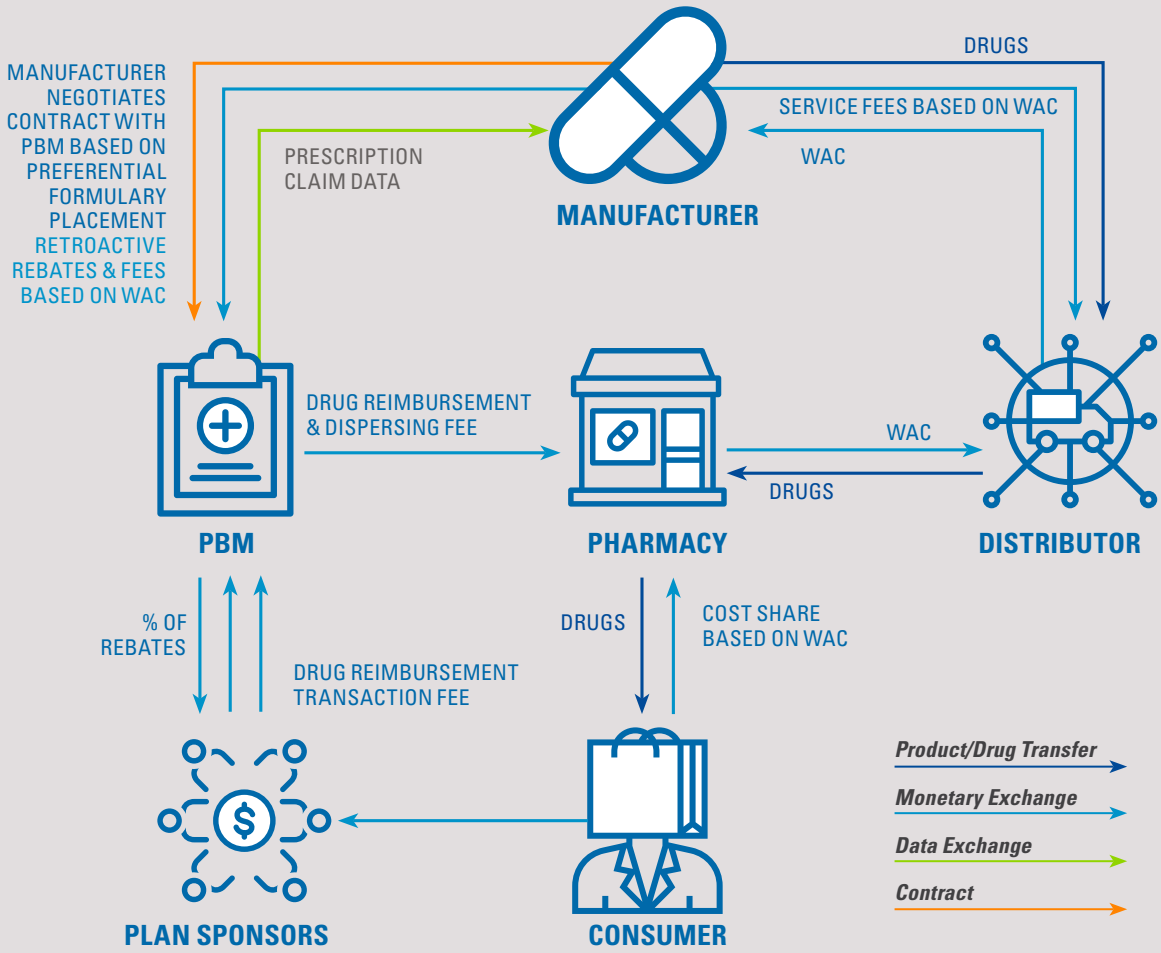
Multiple reasons are given by different people or groups for the high and increasing cost of drugs:

- "America is funding innovation for the world."
- "High prices are due to greedy pharma's ability to raise prices without legal controls."
- "The greed is not limited to pharma companies; there is greed throughout the entire healthcare supply chain including wholesalers, insurance companies, pharmacies, and more."
- "Even though the cost of drugs can be high, it is not a problem because drugs save lives and provide value."
- "The current benefit design and incentive structure contributes to high drug costs."

There is some truth to each of these arguments and some falsehood in each. The reality cannot be distilled to soundbites and doesn't necessarily vilify manufacturers as clearly as the press and politicians would like.

The diagram below shows the complexity of the pharmaceutical supply chain and how products, money, and data flow through the system for managed care plans including Medicare Part D.

Today's Suppy Chain and Data/Dollar Flow for Medicare Part D



The current process is complex with many moving parts and transfer of dollars

Pharmacy and PBM generate the NCPDP DO Claim record at Point of Sale

Rebates are submitted monthly or quarterly

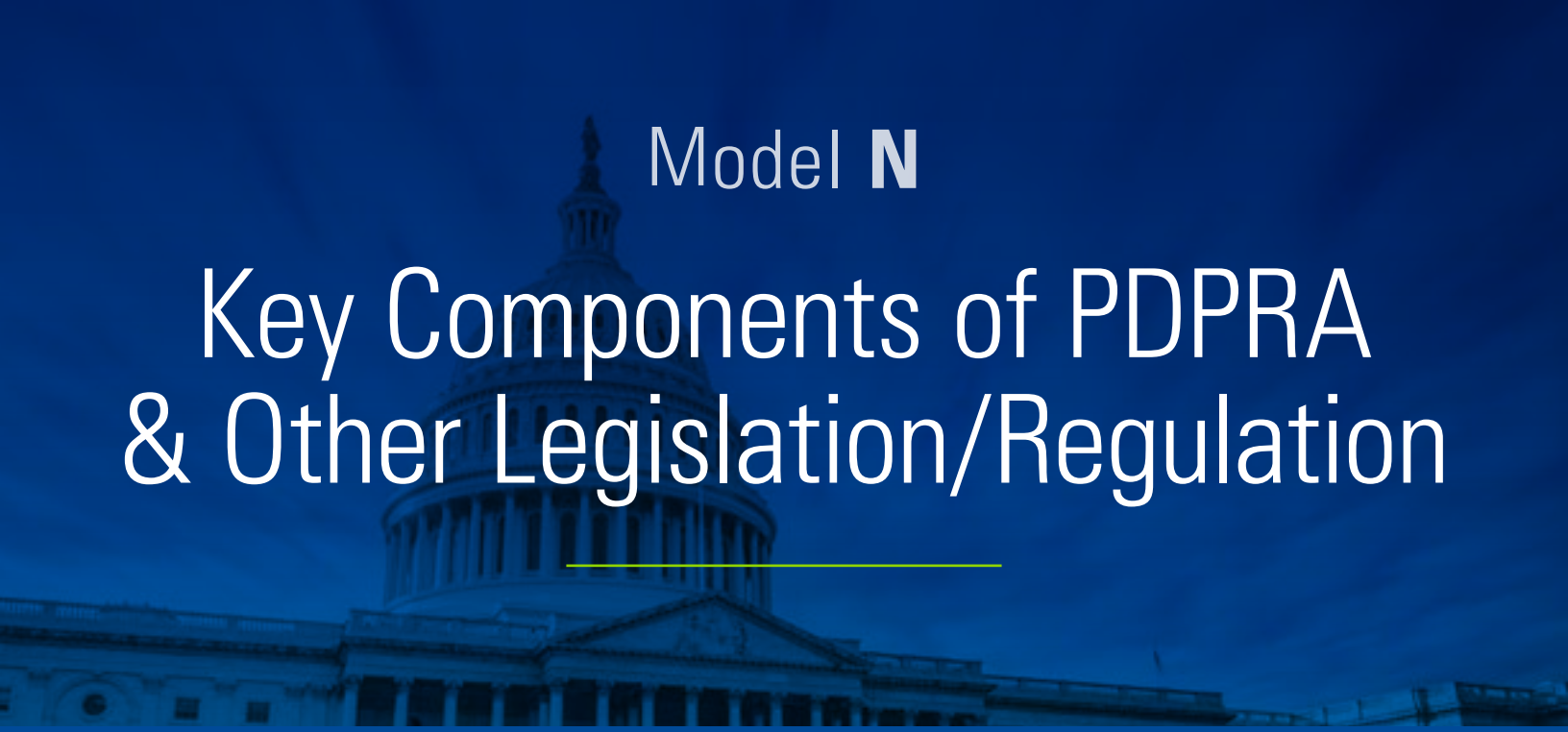
Rebates are paid 30-60 days after receipt

Patient pays co-insurance

PBM converts DO Claim into 4.01 Rebate data set to support their Rebate Invoice

PBM pays Pharmacy in 14 days (typically)

Determines co-insurance (pationet benefit) and Payer Reimbursement



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Key Components of PDPRA & Other Legislation/Regulation

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While PDPRA is working its way through Congress and may undergo significant changes, the version of PDPRA approved by the Senate Finance Committee focused on changes to Medicare Part B and Part D, with other regulatory changes to the Medicaid Drug Rebate Program (MDRP). A common theme for legislation at the federal and state level is emphasis on greater price transparency and reporting.

MEDICARE PART B

Physician-administered drugs and biologics covered under Medicare Part B are reimbursed based on the drug's average sales price (ASP)—which is net of discounts and rebates—plus 4.3%. Part B drugs have been the subject of many recent reform proposals.[1]

PDPRA would seek to reduce Part B drug reimbursement by mandating a rebate from manufacturers to the government if a brand drug's ASP grows faster than inflation, measured by CPI-U. This would apply to prescription drugs and biologicals (not biosimilars or vaccines) administered at physician offices, hospital outpatient departments, and ambulatory surgical center settings.

Other provisions related to Part B include:

- A provision for manufacturers to refund payments to providers for unused drugs
- Inclusion of the value of manufacturer coupons in the determination of ASP

Preparing for these changes and others includes several operational considerations, such as evaluating current systems to ensure that systems can calculate inflation-based rebates and establishing a process to validate Medicare Part B drug utilization.

[1] *Understanding the Bipartisan Senate Finance Prescription Drug Reform Package, Brookings blog, October 3, 2019*

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Medicare Part D

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Part D benefit: Current (2019) and Proposed under PDPRA for 2022

Medicare Part D Changes

The Part D standard coverage benefit for 2019 (on the left) and the proposed standard benefit under PDPRA, that if passed would become effective January 1, 2022.

As currently conceived, PDPRA will have substantial changes to the Part D benefit structure. The goals are to simplify the benefit and realign incentives to encourage more efficient management of drug spending.

Shown above is the Part D standard coverage benefit for 2019 (on the left) and the proposed standard benefit under PDPRA, that if passed would become effective January 1, 2022.

The proposed changes eliminate manufacturer discounts prior to the catastrophic threshold, with enrollees and plans paying all costs until this threshold is reached. After reaching the catastrophic threshold, enrollees would not have any financial obligation. Plans would pay 60%, Medicare 20%, and the drug manufacturer would pay 20%. The intent is to eliminate enrollees' unlimited exposure, increase the exposure to plans to increase their incentive to manage utilization, and require that manufacturers be focused on and provide discounts in these high-cost situations.

Similar to Part B, PDPRA also includes a mandatory rebate for Part D drugs where prices increase more than inflation.

Important operational considerations for the new provisions include establishing a process to scrub/validate invoiced units – which is now typically not done at manufacturers for drugs dispensed under Part B, assessing the impact on volume from changes to Part D, and evaluating financial obligations in catastrophic scenarios, as there is no limit or cap on spending.

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Medicaid Drug Rebate Program

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MEDICAID ENROLLMENT HAS SWELLED

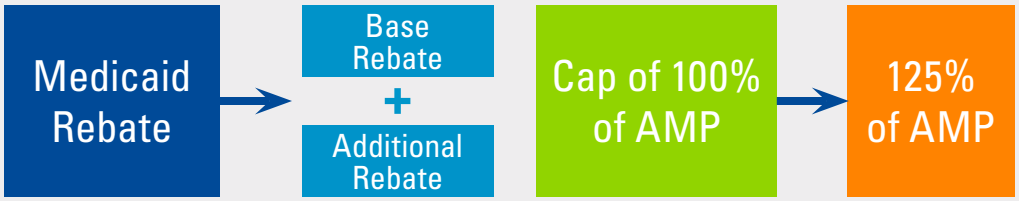
29M
Participants in 1990

75M
Participants in 2018

The MDRP program was initiated in 1990 and requires biopharma manufacturers to enter into rebate agreements with HHS in order to supply drugs at the lowest prices to low-income Medicaid patients. MDRP's importance has grown as Medicaid enrollment has swelled from 29M participants in 1990 to 75M in 2018. In 2019, the Medicaid Services Investment and Accountability Act was passed. It requires that drug manufacturers with Medicaid rebate agreements for covered outpatient drugs must disclose accurate drug product and price information (including, when applicable, AMP, BP, ASP, WAC, and more) and it increases penalties for noncompliance.

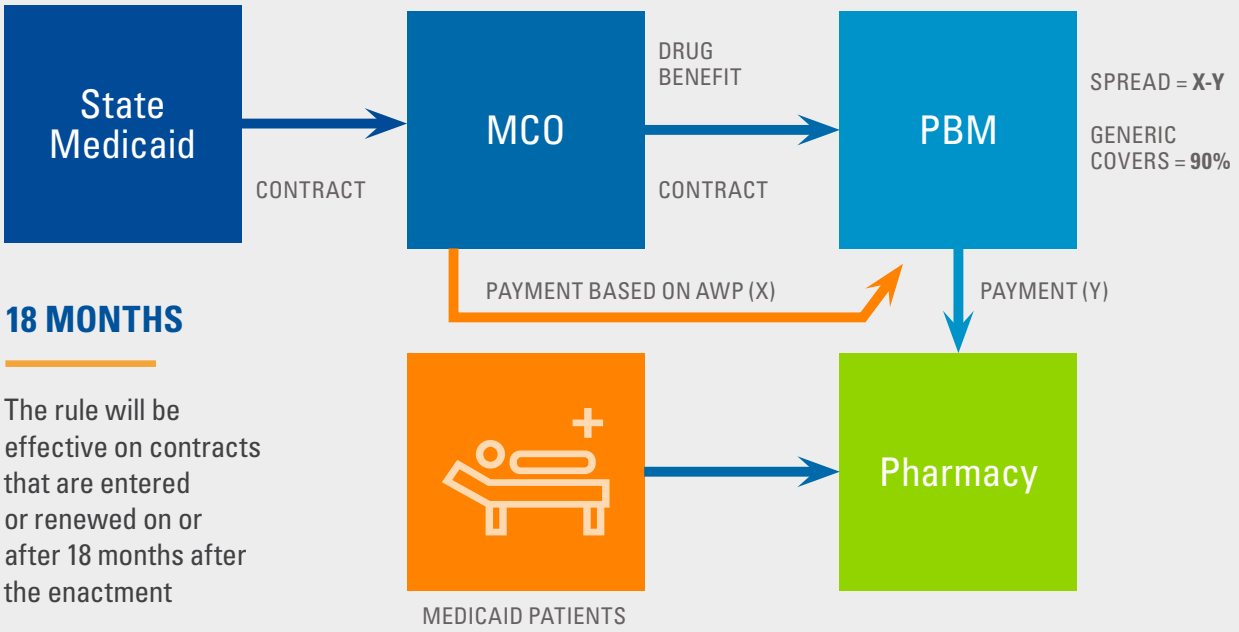
Operational considerations for manufacturers include having tightly controlled master data management to manage product attributes and ensuring the GP system provides the ability to run the GP operation in a timely manner for reconciliation, unbundling (of GP calculations and analysis), and reporting.

Changes to MDRP also include modification of the maximum rebate amount, as shown below.



STARTING OCTOBER 1, 2022 / REVISE SSA SECTION 1927 (C)(2)

Transparency & Preventing Spread Pricing in Medicaid



18 MONTHS

The rule will be effective on contracts that are entered or renewed on or after 18 months after the enactment

In light of these changes, manufacturer liabilities and preparation include:

- Evaluate CODs capping rebate to 100% or almost 100% today
- Evaluate financial impact on additional liabilities
- Adopt a system that provides easy configurability to change the rebate cap
  - > Between December 31, 2009 and September 30, 2022: 100% of AMP
  - > Starting October 1, 2022: 125% of AMP

There are also provisions that begin to allow for risk-sharing value-based agreements under Medicaid for high-cost gene therapies, and rules are being revised to prevent spread pricing in Medicaid.

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Price Reporting and Transparency

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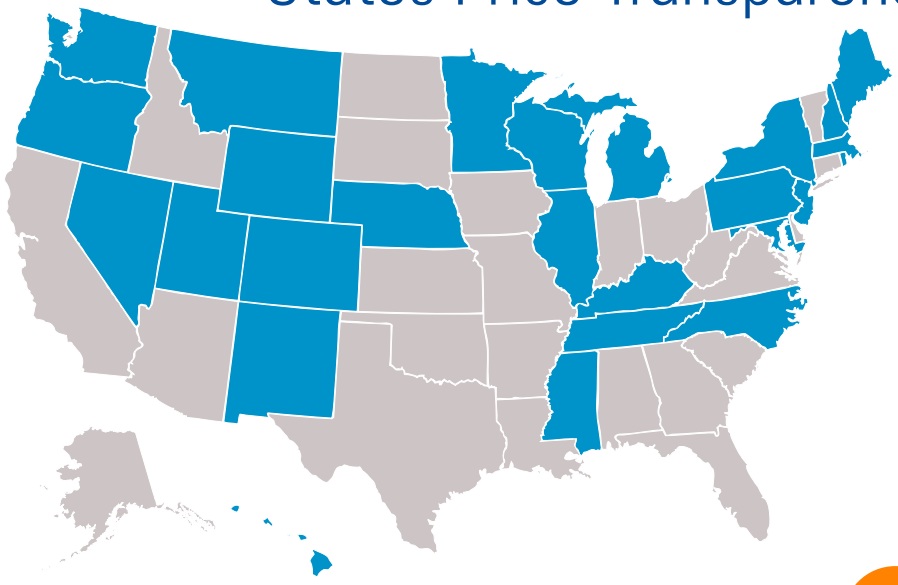
PRICE JUSTIFICATION REQUIREMENTS

Among the types of justifications that might be required are:

- Factors contributing to the price increase
- Total R&D spending on the drug and percentage that came from federal funds
- Spending for materials and manufacturing
- Patents and licenses, or purchasing or acquiring the drug from another company
- Total costs for marketing and advertising the drug
- Total revenue and net profit from the drug each year since approval
- Total revenue and net profit for the period of the price increase
- Total spending on R&D or clinical trials on drugs that failed to receive FDA approval
- Metrics for setting executive compensation

States Price Transparency



TOTAL BILLS | **TRANSPARENCY** 52

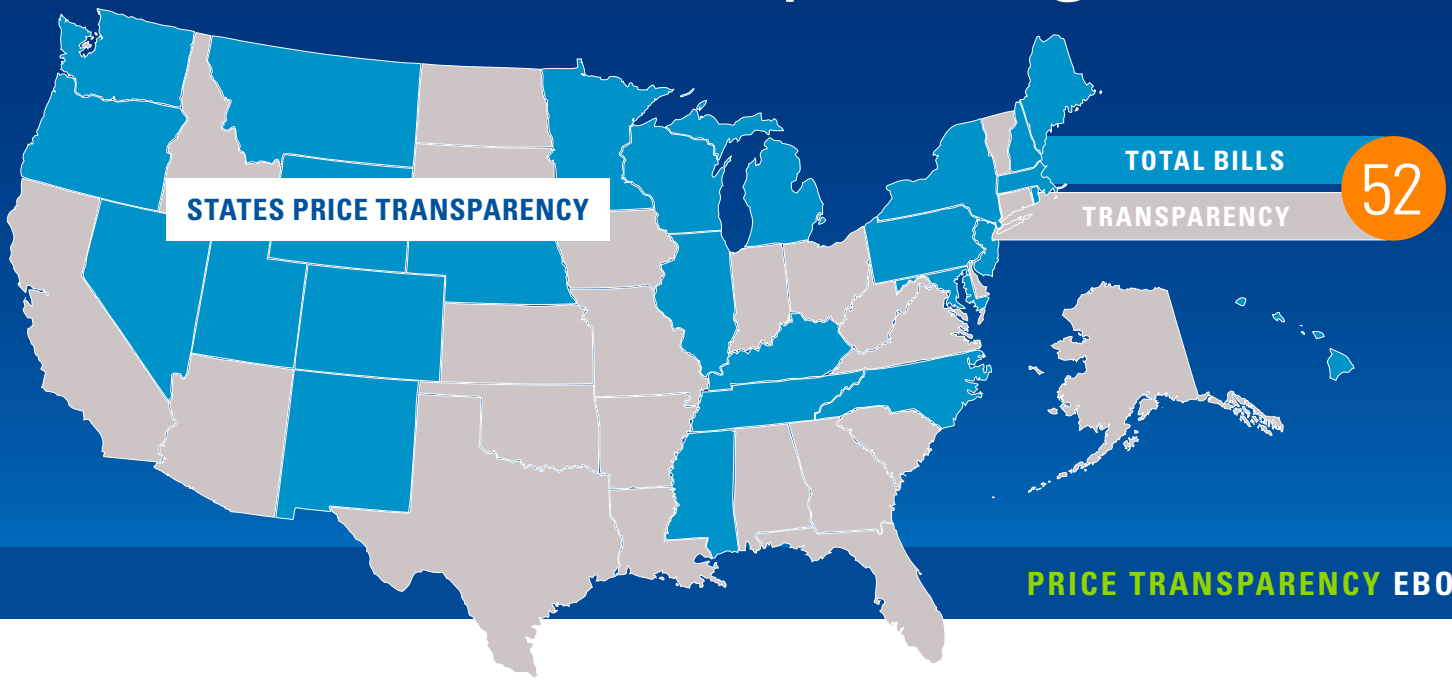
Drug price transparency laws are an important first step toward openness on why drug prices are rapidly increasing. Several states (shown above) have enacted laws that require manufacturers to report the reasons behind dramatic increase in prices.

AS OF AUGUST 1, 2019, 47 STATES HAVE FILED 272 BILLS TO CONTROL PRESCRIPTION DRUG COSTS

Total Bill Enacted	**51**	Drug Price Transparency	**52**
Pharmacy Benefit Manager	**120**	Study	**8**
Wholeslae Importation	**30**	Volume Purchasing	**9**
Drug Affordability Review (Rate Setting)	**14**	Coupons	**8**
		Other	**27**
Anti-Price Gounging	**4**		

Manufacturers may need new measures to evaluate impact and remain complaint when drug prices are increased.

Price Transparency and Reporting



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What to do now to prepare

In light of the known and possible legislative and regulatory changes, manufacturers are asking, "What should we do now?"

By operationalizing reporting needs, building more agility, cultivating flexible and nimble contract operations—which include using the cloud—and continuing digital transformation, organizations will be better positioned for whatever comes next in regulation and price transparency.

RECOMMENDED ACTIONS INCLUDE

ACTION	DESCRIPTION
Operationalize reporting needs	Form cross-functional teams, focus on policy and process, and define the clear government need to be addressed. **CROSS FUNCTIONAL TEAM:** REGULATORY AFFAIRS; LEGAL; FINANCE; PRICING COMMITTEE; GOVERNMENT PRICING; IT **POLICY AND PROCESS:** COMPLIANCE; AUDITABILITY; TRACKING; ADOPTING NEW REQUIREMENTS **GOVERNMENT NEED:** HHS PRICE TRANSPARENCY; STATE PRICE TRANSPARENCY; STATE MEDICAID REPORTING; CMS DDR REPORTING
Build more agility into contracting, pricing, and sales environments	This can come in the form of internal process steps to facilitate greater agility and speed. It can also come from a systems perspective by reviewing software versions to ensure leveraging the most current version with the most robust capabilities.
Cultivate flexible and nimble contract operations	Infuse greater automation into contract automation and compliance processes. This will increase response time, improve agility, reduce waste, and improve efficiency. Also, consider use of the cloud. The cloud can make upgrade steps easier and make compliance simpler.
Continue digital transformation	This includes digitizing processes that create greater oversight for product pricing, improving accuracy of those pricing details and process steps, enhancing validation efforts to reduce revenue leakage, and expanding intelligence offerings and approaches as well as access to data.

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LEGAL	AUDITABILITY	STATE PRICE TRANSPARENCY
FINANCE	TRACKING	STATE MEDICAID REPORTING
PRICING COMMITTEE	ADOPTING NEW REQUIREMENTS	CMS DDR REPORTING
GOVERNMENT PRICING		
IT		

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Conclusion

The focus on drug costs and price transparency is not going away, with payers and patients demanding more information and legislators working on solutions. While the specific elements of legislation and regulation are not known, future changes are inevitable. **To prepare for any eventuality, manufacturers need to create flexible, robust systems that will enable transparency and compliance.** This entails optimizing, automating, updating, and upgrading pricing and contracting applications and infrastructure. By acting now, manufacturers will be in a far better position when the next round of mandates are eventually enacted.

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