

Will New England See Lower Prices from Drug Pricing Transparency Legislation?

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Executive Summary

For decades, New England state legislatures have been the nation's most active on the issue of drug prices. While state legislatures have a strong interest in effectively managing their Medicaid programs—an important cost-driver—New England states have gone beyond Medicaid reform and have attempted to regulate the overall biopharmaceutical company business model, including sales, marketing, and pricing. Attempts have been made to limit and disclose payments to physicians, cap drug prices for cash payers at Medicaid rates, “counter-detail” physicians with information about lower priced drugs, buy drugs from Canada, and to use a single buyer to bulk purchase all drugs in the state.

This paper reviews these New England efforts to regulate the pharmaceutical industry's business model, particularly regarding legislation that seeks to lower drug prices by making certain aspects of the model more transparent. Prior attempts at marketing transparency, for example, failed to make a significant difference in reducing drug prices. This paper assesses the effectiveness of pricing transparency efforts in New England, and their likelihood of success.

Background

The New England states have a long history of attempting to lower drug prices through legislation. In 2000, Maine made national headlines by enacting the Maine Rx drug price control law designed to allow uninsured consumers in the state access to government-mandated Medicaid price discounts. This law survived a U.S. Supreme Court challenge in 2003.¹ But, as current Maine legislators continue to assert that drug prices are wildly out of control and require legislative fixes², the groundbreaking 2000 price control law seems to have had few salient effects.

In recent years, Massachusetts and Vermont have enacted laws touted as legislative solutions to high drug prices, yet both states continue legislative attempts aimed at easing the drug cost burden on consumers and payers. As was the case in every New England state's legislative session for the last 15 years, legislation was in the offing during 2018.³ Over the past two decades Vermont has passed laws to restrict pharmaceutical marketing,⁴ force disclosure of pharmaceutical payments to physicians,⁵ and “counter-detail” providers into prescribing lower cost medicines.⁶ In Massachusetts, legislators enacted a “first-in-the-nation” bulk purchasing law in 1999 that was sold as a solution to both consumers' and the state's fiscal challenges around drug prices.⁷ Furthermore, in a 2009 law similar to Vermont's, the Massachusetts legislature passed a law to ban certain payments and gifts and require disclosure of legal gifts to prescribers valued above \$50.^{8,9}

While these efforts are no doubt well-meaning, past legislative forays into drug pricing regulation seem not to have

brought relief to actual consumers. New England legislators regularly argue that drug prices continue to represent a “crisis” for consumers and for state budgets, tacitly conceding that previous efforts have borne little fruit. The 2018 data from the National Academy for State Health Policy indicates that New England legislatures do not consider the challenge of drug prices to be resolved; during 2018, the six New England state legislatures collectively saw 29 bills designed to address prescription prices.¹⁰

Transparency in Pharmaceutical Operations: From Marketing to Prices

Over the past decade, many policy makers have argued that exposing the somewhat opaque sales, marketing, and pricing practices of pharmaceutical companies would lead to lower costs. A decade ago, the focus was on transparency for payments or gifts to prescribers. Supporters of these disclosures argued that physicians would prescribe fewer high-cost therapies, as the payments from pharmaceutical companies allegedly served as strong incentives to prescribe more expensive ones. As part of Chapter 305 of the Acts of 2008, Massachusetts enacted a Pharmaceutical and Medical Device Manufacturer Code of Conduct banning certain payment to prescribers, but also requiring disclosure of any payments that continued to be legal.¹¹ This legislation's preamble declared that the goal of the legislation was: “An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care.”

Despite the political rhetoric surrounding the passage of this legislation, it seems to have had little or no impact on reducing prescription drug spending in Massachusetts. The law took effect on January 1, 2009 and the first disclosure report was due on July 1, 2010. As part of its reporting on national healthcare expenditures, the Center for Medicare & Medicaid Services (CMS) publishes healthcare spending data by state, per capita by state, and by category of spending.¹² According to that data, per capita spending on prescription drugs in Massachusetts was \$1,046 in 2010, the year of the first disclosure report of physician payments. By 2014 (the last year of currently available data), per capita spending had risen to \$1,250, nearly a 20 percent increase. Furthermore, overall prescription drug spending in the Commonwealth rose from \$983 million in 2010 to \$1.1 billion in 2014, a 17 percent rise.

In addition, during the decade following enactment of the physician payment disclosure law, the Massachusetts Legislature regularly considered numerous pieces bills to lower drug costs, with the strong implication that the marketing disclosure law had made little headway on the issue. Given the cost growth data and the continued political saliency of drug costs and prices, the marketing transparency law seems to have had little or no effect on containing prescription drug costs.

However, the law remains an enormously expensive regulatory burden on the drug and medical device industry, arguably raising drug prices by contributing to the industry's administrative (SG&A) costs. For example, under the law, each company must designate a compliance officer responsible for the company's reporting. The Commonwealth of Massachusetts website lists 699 company points of contact as designated compliance officers responsible for disclosures.¹³ Given the substantial financial penalties for companies that fail to make proper disclosure, it is not surprising that many, if not most, of these contacts for each company are senior compliance attorneys or managers of company compliance programs. In other words, companies are spending vast sums on expensive human resource professionals to comply with a law designed to control drug costs but, according to the data, is having little appreciable effect.

Of course, consumers may be interested in learning about payments to their own physicians. However, an examination of the disclosure documents found on the Commonwealth's website would make it difficult to understand how consumers might benefit from these vast disclosures. The 2015 disclosure report (the latest available) for just the top 20 manufacturers runs 1,272 pages; as indicated previously, 699 companies make disclosures. Therefore, one can assume that a complete report for this data would run tens of thousands of pages.

The Commonwealth's website does allow consumers to run tailored reports and search for their own physician or search by company. In fact, the data generated is itself opaque with very general categories that would provide little insight into whether a particular physician was being unduly influenced by these payments. Payment categories include: Education/Training, Food, Compensation for Bona Fide Services, Grants/Educational Gifts, and CMEs (Continuing Medical Education sessions), third-party Conferences, or Meetings. A consumer seeking to discover whether their personal physician's prescribing decisions are being unduly influenced by the industry will find these disclosures very unsatisfying.

Given the massive amounts of data disclosed as part of the program and the number of industry staff who have registered as designated compliance officials, it seems likely that the industry has been cooperative in complying with the law. Therefore, it is hard to avoid the conclusion that the Massachusetts legislature's attempt at transparency around payments to physicians has been an enormously expensive regulatory burden with little success on lowering drug prices or costs.

One can certainly see the public interest in banning certain excessive payments or inappropriate gifts to physicians that might influence their prescribing choices. However, given that federal law now requires the disclosure of most payments to physicians,¹⁴ the regulatory burden surrounding the disclosure of remaining legal payments under Massachusetts law seems costly, redundant, and furthers no identifiable public interest.

In 2009, Vermont also enacted strict limits on physician payments and gifts by pharmaceutical and medical device manufacturers, as well as disclosure requirements around the remaining legal payments to physicians, such as support for clinical trials or research. Like the Massachusetts law, the Vermont statute assesses fines to companies that fail to submit data but goes one step further by providing for aggressive enforcement of the law by the state Attorney General.

As in Massachusetts, according to CMS's National Health Expenditure Data, the law seems to have had little impact reining in per capita pharmaceutical expenses for Vermont's citizens in the years following enactment. Between 2010 and 2014 (the most recent data available from CMS), Vermont's per capita spending on prescription drugs rose 22 percent.¹⁵ Overall spending on prescription drugs in Vermont rose from \$67 million in 2010 to \$81 million in 2014, a 21 percent increase.

There are conflicting reports regarding industry compliance in Vermont. Earlier reports indicated the Attorney General's office has collected minor awards from generally small- and medium-sized companies that were not sufficiently aware of the new ban on gifts or the disclosure requirement. While the new Attorney General has not retained press releases and information from previous incumbents, press accounts indicate that the largest company to be fined by the Vermont Attorney General is Novartis, which inadvertently provided meals to *two* Vermont physicians while out of state.¹⁶ Given that five states, the District of Columbia and federal law require some disclosure of physician payments, this Novartis infraction gives a sense of the compliance difficulty for the industry, for example, tracking the residency of every physician at a national conference, avoiding illegal payments and capturing legal ones for disclosure under seven different federal, state, and local laws.

One recent report indicated that the Attorney General is investigating certain companies which declared gifts to Vermont prescribers on the federal disclosure database that are legal under federal law but illegal under Vermont law.¹⁷ The fact that these companies made the federal disclosures makes it unlikely that they were seeking to evade Vermont authorities and, more likely, that multiple disclosure laws are causing internal confusion for companies. The Attorney General's office also recently announced an amnesty for companies who had failed to comply with the law, probably indicating that most companies that were out of compliance were smaller companies making unintentional errors.¹⁸

Political leaders in Vermont, however, seem to have abandoned the idea that this previous effort at marketing transparency will lead to significant cost reductions in pharmaceutical spending. The Attorney General's website has little information on the program and there no longer seems to be a website where consumers can obtain a report on their own physician's

acceptance of payments or gifts, making the law appear largely moribund.¹⁹ While required federal disclosures would now capture most payments to physicians in Vermont, there are differences in Vermont law that no longer seem to be captured and disclosed despite company filings.

Most importantly, this year the Vermont Legislature enacted a law permitting importation of prescription drugs from Canada. This was done as a good number of Vermont legislators tacitly acknowledged that previous laws had not made a difference in controlling the prices and costs of prescription drugs. “The price for many drugs, especially specialty drugs, has gone sky-high,” said state Sen. Virginia Lyons, a Vermont Democrat who co-sponsored the importation bill.²⁰

As in Massachusetts, however, now that the Legislature has moved on to other cost control policies such as drug importation, there seems to be no effort to repeal the payment disclosure law that still requires hundreds of compliance personnel from hundreds of companies to track small expenditures and file reports that no one in Vermont seems to be reading or able to access. It seems likely that millions of dollars in industry compliance costs would be saved if states were to repeal their own unique disclosure laws and rely on the federal Sunshine Act that captures most payments to physicians. Given the compliance costs of these previous laws, New England legislatures may wish to consider past statutes and to repeal those that are found to be redundant or ineffective.

Drug Price Disclosure: The Next Physician Payment Disclosure?

Vermont

In 2016, Vermont became the first New England state to enact a drug pricing transparency law.²¹ As the Vermont Attorney General’s office explains: the “law directs the Green Mountain Care Board (“GMCB”), in collaboration with the Department of Vermont Health Access (“DVHA”), to identify annually up to 15 prescription drugs representing different drug classes, ‘on which the state spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs’ pricing.”²² More recently, Vermont has updated the law to consider rebates and other discounts as factors in identifying high-cost drugs. It has also required manufacturers to give advance notice when they plan to market certain costly specialty drugs,²³ a provision similar to a recent Connecticut statute to be discussed later in this paper.

Once a handful of these high-cost drugs are identified, each drug manufacturer is required to submit explanatory information that would provide “justification for the increase”

in the wholesale acquisition cost (WAC), which is more aptly described as the drug’s “list price,” “including all relevant information and supporting documentation” to be submitted to the Attorney General.

Of course, in a market as complex as the one for pharmaceuticals, there exists a multiplicity of factors driving prices, and the weight of each factor varies depending on the specific drug, its therapeutic area, and its particular competitive environment. In their 2018 submissions to the Vermont Attorney General, the nine drug manufacturers whose drugs were highlighted under the statute identified a series of factors that drive pricing decisions, including:

- The value of innovative medicines;
- Cost effectiveness (meaning the economic value to patients given the effectiveness of the drug, compared to other drugs in the same class);
- Size of the patient population for the drug; investments made (including in research and development) and the risks undertaken;
- Return on investment and fiduciary responsibilities post-marketing regulatory commitments and ongoing pharmacovigilance (safety surveillance);
- Creation and maintenance of manufacturing facilities and capabilities, including the ability to address drug shortages caused by production issues;
- Cost of ingredients;
- Competition, including for drugs in the same class; and,
- The rate of inflation.

According to a footnote in the Attorney General’s report, one manufacturer also cited the role of pharmacy benefit managers (PBMs) and other middlemen in pricing decisions.²⁴

The first troublesome component of this statute is the enormous regulatory, administrative, and compliance burden. To provide “all relevant information and supporting documentation” for the pricing decisions on these drugs, manufacturers likely must assemble an internal team with expertise in each of these factors to ensure the accuracy of every submission. This seems an exceedingly burdensome regulatory requirement to explain to a single state the price of a single drug in the company’s portfolio.

The second striking thing about the Vermont statute is that the information it secures and promulgates to the public has little value to those most impacted by the costs of prescription drugs: consumers and payers.

For the average consumer, for example, the “wholesale acquisition cost (WAC)” increase of the 10 drugs identified in 2018 is largely irrelevant information. Even when rebates and other discounts are considered, and a more accurate price is disclosed, of what consequence is this information to a consumer who typically pays nothing to a pharmaceutical manufacturer? Most consumers simply pay a copay or deductible

to the pharmacy. Additionally, the majority of Vermont consumers will not be taking any of these 10 drugs. While some of them are commonly prescribed, none are on the list of the top 10 prescription drugs for 2018²⁵, although Pfizer's Lyrica might make a top 20 list of branded prescription drugs.

Even for consumers who happen to be taking one of these drugs, the price paid by their health plan tells them nothing about what is actually paid at the pharmacy. The deductible or coinsurance paid by the consumer is determined by the consumer's health plan and may or may not vary based upon the price increases of the drug over the past five years. It is perfectly conceivable that a consumer may see lower costs at the pharmacy counter for a drug that was subject to large price increases, and that same consumer might see higher costs at the pharmacy counter for a drug that has been significantly discounted to a health plan.

In fact, over the past two years, 22 states have considered laws banning "gag clauses" in contracts between pharmacy benefit managers and pharmacies that prevent pharmacists from informing a patient that paying cash for a drug would actually be less out-of-pocket than paying a health plan copay.²⁶ In short, consumer out-of-pocket payments do not reflect the prices actually paid by health plans for drugs, calling into question the value of many of these "price transparency" laws that focus on wholesale prices.

Finally, as the previous efforts surrounding transparency on payments to physicians, there does not seem to be a sound economic basis to predict that highlighting 10 or 15 drugs with large WACs or other price increases will lower overall drug costs in the state of Vermont. Most drug manufacturers are public companies that answer to shareholders; companies are unlikely to make key pricing decisions based upon the negative public relations that may result in Vermont from the disclosure of the wholesale price of a single drug. In this politicized environment for drug prices, some companies may tout modest price increases for certain drugs, but it will be impossible to tell if market forces or fear of landing on the Vermont list of offending drugs dictated that conservative pricing decision.

While the law is only two years old, some legislators have already expressed disappointment regarding the value of the information the law has generated.²⁷ That information is too limited and arcane to be of great use to those most concerned about prescription drug costs, including consumers and payers. The law seems intended not to bring meaningful information to Vermonters, but to provide regular, embarrassing reports about pricing practices of pharmaceutical manufacturers on the basis of a handful of drugs and to stir resentment among voters against those companies.

Maine and New Hampshire

Despite the lackluster success of the Vermont law, during 2018, both Maine and New Hampshire enacted drug pricing

transparency legislation. However, in both cases, these laws lack the enormous compliance and regulatory burden of the Vermont law, seek to study the complexity of the overall marketplace, and seem open to considering policy options that might actually benefit their state's consumers and payers.

The New Hampshire law appoints a "Commission to Study Greater Transparency in Pharmaceutical Costs and Drug Rebate Programs" with representation on the Commission from government as well as key outside stakeholders. Part of the group's mission is indeed "analyzing certain critical prescription drugs." But unlike the Vermont law, the New Hampshire Commission is tasked with examining how the price of these critical drugs might impact "patients and their families." This law wisely focuses on key constituencies that are actually impacted by pharmaceutical markets when it tasks the Commission to examine "the impact of drug prices on insurance premium costs, consumer out-of-pocket costs for prescription drugs, and state and county purchasing of prescription drugs."²⁸

Likewise, the Maine law tasks the Maine Health Data Organization to "develop a plan to collect data from manufacturers related to the cost and pricing of prescription drugs in order to provide transparency in and accountability for prescription drug pricing."²⁹ The Maine statute is very short, and it is too early to tell if the information collected by the state will be valuable to consumers and payers. But if Maine adopts the Vermont model that merely seeks to shame manufacturers, it will provide fewer valuable insights for consumers and payers.

Connecticut

Connecticut's drug pricing law²⁹ casts the widest net for disclosures among the different actors in the pharmaceutical marketplace. Disclosures are required not just for pharmaceutical manufacturers, but also pharmacy benefit managers and health insurance plans. While the disclosures are a definitive regulatory and administrative burden for a number of industry sectors, the Connecticut Legislature at least recognizes that pharmaceutical costs are related to the interplay of manufacturers, purchasers, and middlemen. Moreover, the Connecticut law requires disclosure of certain rebate information that sets WAC list prices in proper context.

In addition, the Connecticut Legislature is also aware that the costs incurred by consumers are determined by health plans, not pharmaceutical manufacturers. Of all the disclosures required under various New England transparency bills and laws, perhaps the most consumer-friendly provision is found in the closing sections of the Connecticut law. In its provisions, health plans are required to disclose which drugs may be found on their formularies; any copayments, coinsurance, or deductibles that may be required; how a consumer might access a drug that is not included on the plan formulary;

and any restrictions that are applicable to the drug, such as prior authorization or step therapy, even though the drug is covered. This is extremely valuable information for consumers who may be selecting health coverage and represents the type of transparency that economists would argue makes markets more efficient.

Finally, unlike Vermont, the Connecticut Legislature seems sensitive to the regulatory burden these disclosures will impose. The law requires that pharmaceutical manufacturers be consulted as the state develops the forms used for manufacturer submissions and that the forms be “designed to minimize the administrative burden and cost of reporting on the office and pharmaceutical manufacturers.”

The Connecticut statute also added a disclosure requirement upon drug manufacturers that was recently adopted in Vermont: a submission of drug pipeline information. The justification for this pipeline disclosure is to assess future drugs that may have a “significant impact on state expenditures for outpatient prescription drugs.” Given the recent impact of Hepatitis C drugs upon state Medicaid budgets, it seems to be a reasonable requirement that states, which are required to balance their budgets, receive some notice about key drugs that might impact state budgets. In fact, it is current practice for pharmaceutical manufacturers to regularly brief large commercial payers on their pipeline, so health plans can consider the costs of emerging technology.

Despite the policy logic of planning for future high-cost therapies in state budgets, there are several problems with the design of the Vermont and Connecticut drug pipeline disclosures. First, these states require disclosure based upon price, not impact upon the state budget. High-priced drugs, such as gene therapies, are emerging that, despite their six-figure prices, will have little impact on state budgets because they are designed for very small patient populations.

Second, assessing the fiscal impact of a drug when the drug’s New Drug Application (NDA) is filed will be a very inexact science. Drug prices are typically not established until the drug’s “launch,” which might be a year after an NDA is filed. While there may be some benchmarks for price ranges, such as similar drugs already on the market, competing drugs may come on the market the year after the NDA has been filed that would impact a drug’s launch price.

Finally, it would seem more efficient for pharmaceutical manufacturers to brief federal officials at CMS about emerging technologies that may impact payer budgets. This way, the federal government can then pass that data along to all state Medicaid directors and legislatures. To have 50 different drug pipeline disclosure requirements seems a costly and duplicative compliance exercise.

Like other states, Connecticut also requires that the Office of Health Strategy “prepare a list of not more than ten outpatient prescription drugs that the executive director, in the

executive director’s discretion, determines are (A) provided at substantial cost to the state, considering the net cost of such drugs, or (B) critical to public health.” To their credit, as Vermont did recently, Connecticut required the factoring of rebate payments when considering which drugs should be identified as a “substantial cost to the state.”

Nonetheless, requiring the identification of 10 high-cost drugs based upon the prices paid by payers displays the same infirmities found in the Vermont statute. It represents a significant regulatory burden for companies captured by the statute with little impact upon out-of-pocket or overall drug costs.

Massachusetts

The Massachusetts Legislature is currently in conference committee on larger healthcare bills and both the House and Senate bills contain provisions on drug pricing transparency.

Original Senate Bill

Given that the Commonwealth hosts the largest life sciences cluster in the world, Massachusetts’ original piece of legislation³⁰ around drug pricing transparency, S. 652, represented a highly antagonistic approach to the business model of the life sciences industry and is the type of legislation that should be avoided. Surprisingly, the bill was co-sponsored by an overwhelming majority of the Massachusetts Senate.³¹ The legislation contained numerous infirmities, including crushing compliance and administrative costs, and also sought to bring law enforcement authorities to bear upon drug pricing decisions by using vague legislative language that recommends civil prosecution for companies offering “prescription drugs whose cost is excessively higher than justified.”³²

The preamble to S. 652 telegraphs the authors’ antipathy to the life sciences industry: “An Act to promote transparency and prevent *price gouging* of pharmaceutical drug prices.”

The bill goes on to require the state’s Center for Health Information and Analysis (CHIA) to promulgate regulations identifying prescription drugs that are:

1. the ten costliest drugs by total private health care payer spending;
2. the ten prescription drugs with the highest annual increases in total private health care payer spending;
3. the prescriptions drug [*sic*] introduced to the U.S. market within the past ten years at a WAC of \$10,000 or more annually or per course of treatment; and
4. prescription drugs whose WAC has increased by 50 percent or more within the past five years or by 15 percent or more within the past year.

One important difference between the Massachusetts bill and the Vermont law is that the Massachusetts bill targeted manufacturers developing high cost therapies for rare diseases that tend to have smaller patient populations (#3 above). Ironically,

companies developing these types of therapies, such as gene editing and cell therapy companies, tend to be clustered in Massachusetts.

Once “high cost” drugs are identified, manufacturers would have faced a staggering compliance challenge that goes beyond the Vermont law. Not only would more drugs have been captured under the Massachusetts Senate’s bill’s criteria than Vermont law, but the bill required manufacturers to “report each factor contributing to the drug’s cost or cost increase and the percentage of the cost or cost increase attributable to each factor.” The bill listed fourteen categories of information that must be reported as factors in pricing including:

1. Cost of production
2. Cost of production per dose
3. R&D costs of the specific drug
4. R&D costs paid with public funds including all government grants, subsidies, or other support
5. R&D costs from third parties
6. Price paid to acquire the drug, if not developed by the manufacturer
7. Annual marketing and advertising costs for the drug, apportioned by those activities in the Commonwealth and including lobbying activities
8. Average rebates and discounts and other price concessions off the list price per year
9. Prices charged to purchasers outside the United States, by country
10. Prices charged to direct purchasers in the Commonwealth
11. Prices in the Veterans Administration
12. Average profit margin for the drug for the last five years and expected profit anticipated in the coming year
13. Any information the manufacturer chooses to submit
14. Any information the Center may require

The bill provided for fines of up to \$200,000 for companies failing to provide the necessary information. Finally, the bill encouraged the state Attorney General to review and analyze the information provided by the companies and gives the Attorney General the authority to question and investigate companies making submissions.

If the state’s Health Care Commission decided, after consulting with CHIA, that the cost of certain critical prescription drugs is “excessively higher than justified and jeopardizes the commonwealth’s ability to meet the statewide health care cost benchmark,” the Attorney General is authorized to issue rules classifying the marketing of these drugs as an “unfair (trade) practice” and, presumably, sue the companies. The Attorney General can also enter “into voluntary settlements with the identified manufacturer(s) to negotiate additional rebates or other price concessions.”

The Massachusetts bill suffered weaknesses similar to the Vermont law, but to an even greater degree.

First, the bill did not consider information highly relevant to drug pricing decisions, such as the prices, efficacy, and safety of competing drugs. When a drug enters the market, its pricing is highly dependent upon the nature of the market it is entering. For example, when a drug is the first treatment in a therapeutic class, with no similar competitors, it likely will garner a higher price than similar drugs that enter the market later. Price increases or decreases for that first-in-class therapy will depend upon the safety and effectiveness profiles of competing drugs that may later enter the market. A product that enters the market with significantly lower side effects than the current market leader, for example, may be able to secure a price premium over its competitor. From a business perspective, the omission of this factor by S. 652 is the equivalent of seeking to analyze the price of a Ford F-150 pickup without ever considering the prices and features of the Chevy Silverado or the Toyota Tundra.

Second, despite the mass of information requested by the bill, the submissions by manufacturers would contain little that would be valuable to consumers and payers in Massachusetts, i.e. those most directly impacted by pharmaceutical costs. Consumers and payers would find little use for information about the manufacturing costs of each pill or the price of the pill in, for example, Botswana. Consumers want to know: how much do I need to pay out-of-pocket and how can I get that cost down? Payers want to know: how can I offer an attractive and effective formulary to consumers while keeping costs down? The proposed Massachusetts legislation provides answers to neither of these questions.

Finally, the legal, regulatory, and administrative burden costs of complying with this legislation would be enormous for those companies that are captured by its framework. To assemble a submission under the fourteen criteria and then to weigh the relative importance of the fourteen criteria against one another is a laborious task. Moreover, the Massachusetts Senate bill added criteria that would require much greater data generation and analysis than even the Vermont law: S. 652 requires submission of prices for the drug in *every country in the world*. The number of internal company divisions that would be required to contribute to such a submission would be substantial.

Moreover, the submission would require time-consuming review for accuracy, given the oversight of Massachusetts’s law enforcement officials. It is possible that companies would retain outside counsel from Massachusetts and elsewhere to provide guidance on structuring an accurate submission.

Given the considerable administrative costs that would follow if this bill had become law, it would likely create upwards pressure on drug costs, not the intended downward

pressure. Pharmaceutical manufacturers are among the most highly regulated class of industry, with regulatory and compliance regimes stretching over the entire life cycle of the drug from research, to development and clinical trials, to marketing. These companies also face enormous legal challenges from patent litigation to qui tam suits and settlements. The costs associated with the legal and regulatory oversight of the industry already represent a substantial portion of a company's SG&A expenses. While many of these regulatory rules, such as ensuring the safety of a drug at certain doses, are essential public health requirements, the disclosure of arcane price points for a handful of drugs in multiple states does not seem to be an essential public health requirement that would justify huge compliance expenditures. Higher SG&A costs, which the Massachusetts Senate bill would inevitably drive, certainly put upward pressure on drug prices.

The tone, emphasis, and substance of the Massachusetts Senate bill seemed less directed toward solving the challenge of prescription drug costs and more focused on harassing, interrogating, and scrutinizing an industry that the authors of the bill seem to view with animus.

The Massachusetts Senate modified S. 652 and the Senate bill (S. 2573) that is currently in conference committee contains a number of changes. In this new language, the CHIA's analysis is less focused on a handful of drugs that might have experienced increases in wholesale prices and requires of a broader CHIA analysis of drug cost trends and internal pharmaceutical manufacturer business model practices such as R&D costs, rebate trends, marketing costs, and international cost disparities. While all these changes represent improvements from a very flawed piece of legislation, the Senate language remains a significant compliance burden that would provide very little valuable information to Massachusetts' consumers.

Massachusetts House Bill

The Massachusetts House had competing legislation to the Senate, H.4605 that contains both a drug pipeline notification provision and a drug pricing transparency provision. The House language from H.4605 is now included in the House bill currently in conference committee, now numbered H. 4639.

The provision is considerably shorter than S. 652 and first permits the Massachusetts Health Policy Commission (MPC) to contract with a third party to study the drug pipelines of life sciences companies in order to identify drugs *"that may significantly impact state costs."*

Once these "costly" drugs are identified: *"Any applicant for FDA approval of such drugs shall submit information on the primary disease being studied and the indication, routes of administration, clinical trial comparators, and estimated year of market entry. Manufacturers must also report receipt of orphan drug, fast track,*

breakthrough therapy, accelerated approval or priority review for new molecular entities (NMEs). All data is to be submitted no later than 60 days after receipt of the FDA action date or after the submission of an ANDA to the FDA."

This Massachusetts language is virtually identical the Connecticut pipeline provisions language discussed, and as such is similarly problematic.³³

The House drug pricing transparency provision is significantly less burdensome than S. 652 but is nonetheless ill-advised; CHIA is tasked with identifying no more than 10 outpatient prescription drugs *"that experienced an increase in WAC of 25% or more in that prior year, taking into account any adjustments for rebates paid to the state."* Manufacturers of these drugs then *"must disclose factors that contributed to the increase in WAC in a form that is suitable for public release, as well as aggregate company level R&D costs and other capital costs that CHIA deems relevant."* While the compliance burden of this provision is significantly less onerous than S. 652, it is onerous nonetheless. More importantly, as with the laws in Vermont and Connecticut as well as S. 652, one must ask: After the companies spend significant resources to comply with the law and submit the required information, of what value will this information be to Massachusetts's consumers and payers? The answer is very little value, yet the required disclosures and the concomitant compliance costs will go on for years if not decades.

Conclusion

According to economists, transparency in pricing is essential to the efficient operation of the free market. For consumers to make informed choices, they must understand the value of the product they are receiving, as well as its actual price, so they can compare it with other options that might provide greater value at a lower price. Therefore, legislation labeled as promoting transparency has a certain superficial appeal on the basis of its purported association with market-based economics.

However, in the U.S. pharmaceutical market, most consumers of prescription drugs are not the actual purchasers. Consumers may pay copays, coinsurance or deductibles at the pharmacy counter that partially offset the cost of the drug, but the primary purchasers of drugs in the United States are government and commercial health plans. Moreover, the out-of-pocket costs consumers pay are not always closely related to the overall price their health plan pays for a drug.

Further, health plan payers do not pay the prices listed on a drug company invoice. Most payers have vast data about the safety and effectiveness of competing prescription drugs and they negotiate rebate payments from drug companies as a way of purchasing each drug at the optimal price given its value. While these rebate negotiations are not transparent to patients and consumers, they generally are transparent to the actual

payers who negotiate rebates on specific drugs by weighing data from clinical trials, medical records and published studies, and comparing it with data from competing drugs.³⁴

Moreover, because of the growth in rebate payments and other discounts to middlemen, the spread between the WAC and what payers actually pay continues to grow,³⁵ making knowledge of WAC increasingly obsolete as a benchmark for drug costs. Many current drug transparency laws do not consider the policy implications of this rebate growth and how reforms of certain payments to middlemen might benefit consumers or payers.

For payers, the pricing transparency bills discussed provide redundant information and do not assist them with their key challenge: lowering drug costs without compromising patient access. Payers want to construct a formulary that has broad appeal to consumers and offers popular and effective drugs, while keeping costs, and premiums, under control. It is difficult to envision how the required disclosure of WACs on a handful of drugs assists payers with these goals, although some payers may consider the political focus on drug costs as beneficial leverage in their negotiations.

The second most important infirmity of some drug pricing transparency legislation is the regulatory and compliance burden. Most drug manufacturers are public companies and disclose vast amounts of information concerning their various cost centers, including sales, marketing, and R&D, in their regular U.S. Securities and Exchange Commission filings, particularly their 10-K and 10-Q filings. These filings provide a treasure trove of information about the internal sales, marketing and pricing practices of the industry. Providing state-by-state filings with differing criteria for specific drugs would be, and is, a very costly administrative burden.

In New England, New Hampshire's drug pricing transparency law holds the most promise of finding specific solutions to the drug cost challenge that might actually assist consumers and payers. The New Hampshire law (rightfully) assumes that the marketplace is complicated and seeks information on a complex mixture of producers, payers, and middlemen. Additionally, it creates a commission to study potential constructive solutions, rather than installing a burdensome regulatory regime. It should also be noted that Connecticut's requirement that health plans disclose to consumers information about drug formularies and cost sharing is another very consumer-friendly provision.

The weakest and most harmful of New England's drug pricing transparency proposals was Massachusetts' S. 652. Not only did the bill strike directly at some of the Commonwealth's most innovative biotechnology companies by targeting high-cost therapies for serious diseases that tend to have small patient populations, the proposed regulatory burden imposed was so vast as to have an element of farce. Did

Massachusetts Senators really propose that compliance lawyers in the headquarters of life sciences companies spend their time contacting the company's sales managers for countries like Botswana, Togo, and Brunei to assemble a submission to the Commonwealth of Massachusetts on worldwide, nation-by-nation prices for one particular drug?

Finally, while health care cost growth is a genuine challenge, it is not clear why prescription drug costs and prices are a particularly acute crisis compared with other health care sectors. Recent data indicate that national health care costs have grown at an annual average of 4.7 percent between 2006 and 2015. Cost growth for prescription drugs during the same period averaged 4.8 percent, while cost growth for hospital care was 5.5 percent. During this time, costs for professional services rose 4.3 percent and net health insurance costs rose 5.6 percent.³⁶ Drug cost growth for 2017 has dropped even lower. Recent data indicate that, when rebates and discounts are considered, prescription drug cost growth was 0.6 percent last year.³⁷

Drug costs do not seem a significant outlier or cost driver for the overall system, so one might ask why the biopharmaceutical industry has attracted such scorn from New England legislatures. It is possible that because local hospitals, physician groups, and even health plans are local employers, politicians find it easier to scold out-of-state drug companies for their pricing policies. This theory, however, does not explain the hostility of many Massachusetts Senators to the local life sciences industry, one of the state's most important employer segments.

Yet, while drug costs are not contributing disproportionately to overall health costs, there are subsets of patients who have seen significant growth in their spending on prescription drugs. Those familiar with the emerging therapies coming out of biopharmaceutical laboratories will indeed recognize that significant drug cost challenges for certain patient populations do indeed loom.

Most consumers of prescription drugs see very small out-of-pocket costs. During 2017, 80 percent of consumers had out-of-pocket costs below \$10 with a full 31 percent seeing no cost sharing at all.³⁸ However, half of all new drug launches in 2017 were for "orphan drugs," or higher-cost therapies designed for smaller patient populations. Patients using these specialty medications do indeed require some cost relief, as during 2017, 3.4 million prescriptions were written for patients who experienced out-of-pocket costs above \$500 and with an average cost of \$1502 per prescription.³⁹

Given these data, New England's legislators may want to consider exploring more constructive solutions to these genuine, emerging challenges. Some of the challenges might include:

- How will payers and patients pay for emerging gene and

cell therapies and other high cost therapies that will carry six figure price tags, but hold the promise of curing dreaded diseases? The White House drug plan advocates that the federal government lead the way in developing solutions to this challenge by having Medicaid and Medicare rely “more on value-based pricing by expanding outcomes-based payments.”⁴⁰

- How can the growing discounts and rebates obtained by pharmacy benefit managers be passed on to consumers to lower their out-of-pocket prescription drug costs? One recent report from Ohio Medicaid, for example, pointed out that pharmacy benefit managers had pocketed \$223 million in discounts obtained for Medicaid managed care plans.⁴¹ This report and others seem to indicate middlemen are not passing on significant discounts to consumers or payers.
- Or, alternatively, how can rebate payments be curtailed or limited so list prices for drugs reflect something close to their actual price, causing out-of-pocket costs to drop with the reduced list prices? While the details are yet to be released, the White House drug plan promises to require “plans to share a minimum portion of drug rebates with

patients,”⁴² a reform that holds the promise of significantly reducing out-of-pocket costs for patients taking higher cost drugs.

- How can state and federal Medicaid laws be reformed so that Medicaid programs do not pay for drugs “by the pill,” but based upon the health care value that the pill brings to the program.

New England is home to the most innovative life sciences companies in the world. Policy makers should not take this industry for granted. Some recent data indicate that hiring in the life sciences industry is softening.⁴³ This trend can also be seen nationally.⁴⁴ Bringing new therapies to patients will be a challenge of immense proportions. Cost and reimbursement regimes must be developed for these therapies that provide access, but do not bankrupt payers. Innovative policy proposals that are constructive and might bring patient access to new technologies should take precedence over legislation designed to score political points or drive grievances against a valuable industry sector.

Endnotes

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30. On 6/5/18, S. 652 was sent to study and new language on drug pricing was included in S. 2573, the Senate healthcare bill now in conference committee.
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32. <https://malegislature.gov/Bills/190/S652>
33. See pp. 10–11.
34. When PBMs are contracted to negotiate drug rebates on behalf of health plans, there is some controversy about whether those PBMs are transparent with their clients about rebate payment levels.
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Pioneer Institute is an independent, non-partisan, privately funded research organization that seeks to improve the quality of life in Massachusetts through civic discourse and intellectually rigorous, data-driven public policy solutions based on free market principles, individual liberty and responsibility, and the ideal of effective, limited and accountable government.

