NASHP's Proposal for Imposing Penalties on Excessive Price Increases for Prescription Drugs

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Introduction

Price increases contribute substantially to overall spending on prescription drugs in the United States, leading many states to explore opportunities to impose penalties on drug manufacturers for "excessive" price increases. Even though drugs' launch prices are already very high in many cases, prices for single-source (branded) drugs regularly increase above the rate of inflation. Price increases have been found to contribute substantially to spending by health plans and states for drugs purchased outside of the Medicaid program.[1]

In addition to the potential for savings, two other factors make price increases an attractive target for regulation. First, although defining what constitutes an excessive or unfair *launch* price for a drug is highly controversial, defining an unjustified price *increase* is more tractable because there is a clear basis for comparison: the rate of general or medical inflation. Second, there have been many reports of extremely large price increases for which manufacturers have offered no justification—Turing Pharmaceuticals' Daraprim being the highest-profile example.[2] Price increases therefore tap into public concerns about profiteering in the pharmaceutical industry.

In this policy brief, we provide a roadmap for states designing legislation to regulate excessive price increases. We focus on two existing models: the "Massachusetts Model," as outlined in legislation proposed in Massachusetts in 2019 and spearheaded by Gov. Charlie Baker; and a protocol developed by the Institute for Clinical and Economic Research (ICER) to identify large price increases that are unsupported by new evidence about a drug's value. We describe these models and offer recommendations for states considering adopting one of these or a hybrid approach, including recommendations aimed at safeguarding against legal challenges.

Content

1. Overview of the Massachusetts Model

Legislation proposed in Massachusetts — H.B. 4134, "An Act to Improve Health Care Through Investing in VALUE" — would use the Commonwealth's existing Health Policy Commission to evaluate excessive price increases for prescription drugs.[3] Key design features of the Massachusetts model are summarized in **Table 1**.

Under this proposal, the state identifies drugs for review by analyzing public and private payer data in Massachusetts to find drugs with current average total costs of $50,000 or more per year per patient. The analysis is limited to drugs approved by the US Food and Drug Administration (FDA) during the preceding five calendar years. A list of these drugs is given to the Health Policy Commission, with notice to the manufacturers. The report is also made publicly available, including drug-specific average annual gross costs per user for public and private payers in the state.

The commission's task is to determine whether each drug's list price has increased more than 2 percent above general inflation above a reference price (details in Table 1). The price examined is the wholesale acquisition cost, or WAC. The reference price is the price on Oct. 1, 2019 or, for drugs launched after that date, the date the drug was first marketed.

For each listed drug identified as having an excessive price increase, the commission requires the manufacturer to submit the following information:

1. The drug's WAC increases over previous five calendar years;
2. The manufacturer's total research and development (R&D) and capital expenditures for the most recent year for which final audited data are available;
3. A narrative explaining factors contributing to reported changes in WAC in the past five years; and
4. Any other information the manufacturer wishes to provide.

Importantly, proprietary data provided by manufacturers is not made public. If a manufacturer fails to promptly supply it, it may be subject to penalties, including a $500,000 fine. The commission may also request additional relevant information that they deem necessary for identifying a drug's proposed value.

Using the information supplied, the commission "may identify a proposed value" for the drug and determine whether the drug's pricing "is potentially unreasonable or excessive in relation to the commission's proposed value." It may incorporate (but not wholly rely on) third-party analyses, such as cost-benefit analyses. Should a third party be hired by the commission to undertake cost-effectiveness analysis or other research to define a product's value, they must describe methodologies used, assumptions and limitations of the analysis, and outcomes for affected subpopulations. Drugs ultimately confirmed to have excessive price increases in relation to the commission's proposed value of the drug are subject to a tax penalty, described below.

When the commission determines that a price is potentially unreasonably or excessive, it conveys this decision and the basis for the decision to the manufacturer, which has 30 days to provide further information to justify the pricing or correct errors. The commission may also

seek input from other relevant parties (e.g., patients, providers, provider organizations, payers). Information used by the commission to assess the drug's proposed value is provided to the manufacturer for review and input.

No later than 60 days after receiving the manufacturer's feedback, the commission issues a final determination on whether the pricing of a drug is unreasonable or excessive in relation to the commission's proposed value of the drug. If it is, the manufacturer pays a penalty of 80 percent of the "excessive" amount of the price increase for each unit sold for distribution in Massachusetts, determined at the beginning of the calendar quarter. The penalty is structured as a tax and paid to the state commissioner of revenue. Units that were excessively priced and sold outside of Massachusetts are not assessed the penalty (manufacturers can claim credit for this amount on the return for the tax period during which units were sold). Manufacturers are subject to the penalty if they (1) maintain a place of business in Massachusetts or (2) sold, directly or through another entity, over $100,000 in products in Massachusetts in the past 12 months.

Notably, the Massachusetts model may represent a challenge for states due to its reliance on existing infrastructure (i.e., all-payer claims data and a commission tasked with evaluations) to identify candidate products and assess their value. We include several suggested modifications to the Massachusetts model below to address some of these challenges.

2. Overview of the ICER Model

Using private philanthropic funds, ICER has developed a detailed methodology for identifying drugs with large, "unsupported" price increases.[4] The method differs substantially from that of the Massachusetts model (Table 1**)**. ICER's model identifies candidate products for which states may seek price relief, allowing states to determine an effective and appropriate penalty for products with unsupported price increases. States could, for example, adopt a law like Massachusetts's imposing a tax on drugs sold in the state that ICER identifies as having unsupported price increases.

ICER's protocol (details in Table 1) identifies up to 13 drugs that have experienced substantial price increases over a two-year period that do not appear justified by new evidence concerning the drug's clinical or economic benefit or other factors such as increased production costs. ICER performs the work of identifying drugs, focusing on those that contribute substantially to drug spending in the United States and that experienced large price increases in the past two years. Specifically, it begins by identifying the top 100 drugs by net sales in the United States across all payers. It then identifies which of these 100 have experienced increases in WAC over the prior 24 months that exceed twice the rate of medical care inflation. For products meeting these criteria, ICER goes on to evaluate changes in net price after rebates and discounts. ICER then ranks the drugs by total spending impact (change in net price multiplied by total sales volume) and selects the top 10 drugs from this ranking for evidence review.

In addition, up to three other drugs may be added to ICER's review based on four criteria, which may be assessed through public and stakeholder input:
(1) Drugs with extremely high price increases that do not have substantial national budget impact (i.e., because the drug is used by only a small number of patients);

(2) Drugs used by millions of Americans with price increases just below stated thresholds;
(3) Drugs whose price increases have important affordability implications for individual patients; and
(4) Drugs whose price increases raise concerns about the fairness of the price increases.

Once drugs are selected for evidence review but before candidate drugs are made public, ICER contacts manufacturers to provide input regarding new clinical data or other information that may justify the observed price increase. This information may be:

- New clinical evidence over the prior 36 months that demonstrates improved clinical or economic outcomes;
- New evidence relating to comparator therapies that the manufacturer believes indicate new evidence of relative clinical advantages of their drug; or
- Other potential justifications for a price increase, including new information within the prior 36 months related to:
    - A large increase in costs of production;
    - Large price savings attributable to the drug in other parts of the health system; and
    - All other reasons deemed relevant by the manufacturers.

Using this information, ICER determines which existing or new indications account for 10 percent or more of drug utilization and creates a baseline of known safety and effectiveness data from the drug label. ICER then performs an independent systematic review or manufacturer-submitted information to identify new benefits and harms of the treatment under consideration for each relevant indication. It then assigns a quality rating to the new evidence and the magnitude of "net health benefit."

Finally, ICER considers this information and makes a decision about whether the price increase is "supported" or "unsupported" by new evidence. To be "supported," there must be new evidence of "moderate/high quality" showing "a substantial improvement in net health benefit." That means that although ICER will consider non-clinical factors such as a manufacturer's increased production costs, such factors evidently cannot drive a determination that a price increase is "supported." Manufacturers are given several opportunities to offer data to support price increases or to correct potential errors in calculating net revenues that resulted in their being included on the candidate drug list.

The reports that ICER makes public are highly transparent, and include information on net sales revenue, change in list price, and change in net price for the 10-13 products evaluated, in addition to a description of ICER's analysis. The first of these reports, published in October 2019, is available on ICER's website along with methodological details.[5]

Table 1. Key Design Features of the Massachusetts and ICER Models

	Massachusetts	ICER
Definition of excessive price increase	"Excessive price increase" = amount by which a drug's WAC exceeds the inflation-adjusted reference price plus 2% of the reference price for each 12 months elapsed since the date the reference price was determined.* Reference Price = WAC on 10/1/19 or, if drug was launched after that date, the date first marketed.	"Unsupported price increase" is an increase in net spending exceeding twice the rate of medical inflation that is not supported by new evidence of moderate or high quality of a "substantial improvement in net health benefit."
Penalty	80% tax on any excessive price increase, for all units ultimately sold in Massachusetts; amount is calculated per unit at the beginning of the calendar quarter. Additional penalties for obstructing the commission's work.	Not applicable (no penalty described).
Transactions covered	Units sold "directly or through another person, for distribution in the Commonwealth"	Analyses examine all US sales.
Entities covered	Manufacturers that (1) sell drugs "directly or through another person, for distribution in" Massachusetts and (2) maintain a place of business in Massachusetts or (3) sold, directly or indirectly, over $100,000 across all products in Commonwealth in the past 12 months.	Not applicable (no penalty described)
How costly drugs are identified for review	Current average annual gross cost per user >$50,000 for products approved by the FDA within the last five years.	Multi-step process to identify up to 13 drugs: Start with top 100 drugs by net sales in the Unitd States across all payers. Identify drugs with 24-month increases in WAC greater than twice the rate of medical inflation. Rank these drugs by total net spending impact (annual sales volume multiplied by increase in net price**); submit the top 10 for review. Add up to three other drugs based on additional criteria and public input.***
How an excessive price increase is determined	Finding that price increase is "unreasonable or excessive in relation to the commission's proposed value of the drug"	Finding that there is no new evidence of moderate/high quality showing "a substantial improvement in net health benefit."
Types of information considered	To identify costly drugs: Gross drug costs per patient from public and private payers in Massachusetts	To identify costly drugs: Net US sales across all payers used to define top 10 drugs with highest budget impact

	To determine excessive price increases: WAC in past five years; manufacturer's total R&D and other relevant capital expenditures in most recent year; manufacturer's summary of factors contributing to price increases in past five years; other information manufacturer wishes to provide. To identify proposed value of drug: Methods not clearly specified; option to rely on third-party cost-effectiveness evaluation or other research (presumably using data supplied by the manufacturer) is noted.	(candidates initially selected from the top 100 highest revenue drugs that had WAC increases greater than two-times inflation). Stakeholder input used to identify up to three more drugs. To determine unsupported price increases: Compile and evaluate the quality of new evidence (past 36 months) showing improved clinical or economic outcomes, relative clinical advantage over competitor drugs, large increase in production costs, or other reasons manufacturer deems relevant.
Entity making determination	Costly drugs: State Center for Health Information and Analysis Excessive price increases: State Health Policy Commission	ICER
Manufacturer's involvement	Furnish requested information, including reasons for price increase; review and offer feedback on tentative determinations.	Furnish information regarding new clinical data or other information that may justify price increases; offer corrections to price data.
Information made public	List of drugs referred for review and gross cost per user for each (manufacturers' data remain confidential)	List of drugs selected, net sales revenue, change in WAC, change in net price. Information remains confidential until all analyses are completed and publicly released.

* For example, consider a 2% general inflation rate and a drug that costs $1,000 per user on 10/1/19. The next year, the inflation-adjusted price would be $1,020 and the maximum allowable price would be 1020 + (0.02 x 1000) = $1,040. The excessive price increase — that is, the amount subject to the 80% tax — would be any amount above $1,040. Inflation adjustment uses the consumer price index for all urban consumers in Boston. WAC = wholesale acquisition cost.

** Net price = price after discounts, rebates, concessions to wholesalers and distributors, and patient assistance programs.

*** Additional criteria: (1) extremely high increases but small national budget impact; (2) widely used drugs with price increases right below stated thresholds; (3) price increases with "important affordability implications for individual patients;" and (4) price increases raising fairness concerns.

3. What Criteria Should States Apply in Choosing an Approach to Regulating Price Increases?

As states consider approaches to address price increases, it is worth considering how application of each of the reviewed models would work in practice. Both models address price increases and avoid the legal obstacles encountered in Maryland's prior attempt to regulate price gouging. But they target different products and vary in their administrative complexity.

In choosing between them and/or making modifications to their core design features, states may wish to consider **four decision criteria**: **reach, effectiveness in deterring price hikes, administrative feasibility, and vulnerability to legal challenge** (see **Box 1**). Below, we apply these decision criteria to the two models and provide recommendations for states.

Box 1. Decision Criteria for Choosing a Model Design

1. **Reach**: To what extent does the approach reach the drugs that are of greatest concern to policy makers? The design considerations that most directly affect this are the criteria triggering state review and the criteria triggering a determination that a price increase is excessive.

2. **Effectiveness in deterring price hikes**: How likely is it that the model's design will give manufacturers adequate incentive to keep price hikes below the allowable limit? The nature and size of the penalty imposed for exceeding the limit is the primary consideration, but also important are the likelihood of receiving a penalty and the extent to which the manufacturer can ultimately avoid bearing the cost of the penalty.

3. **Administrative feasibility**: How much of an administrative burden would the approach impose on the state? The key considerations here are how complicated the excessive-price determinations are and who will make them.

4. **Vulnerability to legal challenges**: What is the potential for drug manufacturers to successfully challenge the law in court? Can the model be adapted to minimize its vulnerability to such challenges?

While both models are promising means of regulating excessive price, two limitations common to both may prompt states to consider whether additional policies should be enacted to reinforce them.

- First, neither model directly lowers prices for consumers at the pharmacy. However, states could choose to earmark funds raised under the statute for consumer relief (through lower premiums or increased benefit generosity), or the statute could expressly provide for tax credits or payments to consumers based on their reported drug expenditures for the year.
- Second, neither model affects the price at which a manufacturer initially launches a new drug. (It is notable, however, that the Massachusetts model implicitly considers the cost-effectiveness of a drug's launch price, as we discuss below in Section 8.1.c.).

Manufacturers could respond to the adoption of a law regulating price increases by launching new drugs at a price higher than they otherwise would choose, though market forces or other state legislation may limit their ability to do so. NASHP has proposed an international pricing index approach for addressing launch prices, which would complement statutes focused on price increases.

4. Model Reach and Drugs Targeted

Because the two approaches differ in their drug selection criteria, they vary substantially in the number and type of products targeted. The ICER model reaches only 10-13 drugs per year. However, because they are chosen from among the top 100 drugs in total net sales, they are commonly prescribed drugs, including many "blockbusters." Indeed, the products ICER recently identified as having "unsupported price increases" regularly appear on state transparency sites and drug lists for products with the highest total costs and/or highest total cost growth. The

Massachusetts model reaches a much larger set of drugs, however, they are primarily very expensive drugs that are prescribed to a small number of patients.

To better understand the differences between the models, we performed a simulation using nationwide MarketScan data for commercial payers in 2017 (see **Box 2**).[6] **Our analysis found that the Massachusetts model may have greater reach in terms of impact on total outpatient drug spending, but the ICER model reaches drugs taken by more patients.** Our simulation does not permit conclusions to be drawn about which model would ultimately reduce drug costs more, as that depends on subsequent exclusions under the Massachusetts proposal based on application of the review criteria (FDA approval timeframe and "value" assessment). However, it shows that the products targeted by each approach vary substantially.

Box 2: Simulation Results - Reach of the Two Models

We first generated the list of drugs that would be candidates for review under the **Massachusetts model**. For commercial payers, presumably the largest group that would be affected by the bill, 101 orally-administered drugs were identified representing **15 percent of total outpatient pharmacy spending** and 0.4 percent of medication users. Additionally, 41 physician-administered drugs were identified representing **35 percent of total outpatient medical spending on physician-administered drugs** and 0.6 percent of all enrollees. (Notably, the Massachusetts model focuses on drugs that were approved by the FDA in the last five years. It is not clear if this five-year window includes products with new indications during that period or is based on the initial drug approval date. In either case, many of the products we identified would be excluded from consideration based on this further restriction.) These findings suggest that even without the five-year restriction, **the Massachusetts model would not include many commonly prescribed drugs. However, the model could have a sizeable impact on total outpatient prescription drug spending,** depending on the number of products remaining under consideration after exclusions. The model also includes a large number of products used to treat rare and complex illnesses (e.g., cancer, multiple sclerosis, or cystic fibrosis) for which patient access to medicines is a serious concern.

We then examined drugs that were identified as having unsupported price increases under the **ICER model**. There was minimal overlap between the two models, even before restrictions were made to either list. Notably, no drugs included on ICER's final list of drugs with unsupported price increases overlapped with the candidate list from the Massachusetts model. (Revlimid was included in both candidate lists but could be excluded from the Massachusetts model depending on how the FDA approval exclusion is applied; this drug was ultimately found to have clinical data that might have justified its price increase.) Using the MarketScan data for commercial payers, we find that spending on the seven products that ICER found to have "unsupported price increases" represented **11 percent of total outpatient pharmacy spending** (for Humira, Lyrica, Truvada, Cialis, and Tecfidera) and approximately **10 percent of total outpatient medical spending on physician-administered drugs** (Neulasta and Rituxumab). Thus, **ICER's identified drugs represent larger patient populations than those targeted by the Massachusetts model but a potentially lower share of total outpatient prescription drug spending, depending on the number of drugs ultimately retained in the Massachusetts model**. Nevertheless, ICER's drugs represent affordability challenges for states: all seven of them appeared on lists of drugs with the highest total costs and/or highest total cost growth published by states.

It is especially difficult to gauge the ultimate reach of the Massachusetts model because little information has been made available about how the review body would determine the "proposed value" of a drug. The proposal alludes to cost-effectiveness analyses, which evaluate the clinical benefits of a drug in relation to its cost—but also indicates the commission would look at the manufacturer's costs to produce the drug.

In both proposals, there is a tradeoff between maximizing reach and keeping assessments of excessive price increases tractable. The wider the list of drugs that may be evaluated, the greater the potential impact — but the greater the burden on states to do the work of evaluating them. States should therefore consider how to "right-size" their candidate drug lists in order to ensure that further assessments of excessive price increases are feasible. The Massachusetts proposal's focus on products approved by the FDA within the past five years helps limit the administrative burden, but may result in excluding older drugs that represent a larger strain on state budgets or that had large increases in net prices. For the ICER model, the limited number of products under consideration is a concern as there may be drugs that have similar budget impacts but fall out of range for inclusion. ICER's limit of 13 drugs per year is probably based primarily on the time needed to evaluate clinical evidence and work with manufacturers and the public — not its best guess about the number of drugs with large, impactful price increases.

The question of which model better reaches the drugs that are of greatest concern to policymakers raises another question: should policymakers be concerned about large price increases that are supported by evidence that a drug's clinical value is higher than previously thought? Neither the ICER nor the Massachusetts model targets such drugs — but states could adopt alternative criteria that simply look at the drug's overall cost and the size of price increases. Arguably, drugs that are delivering good value — including by averting other costs in the health care system — may be worth the money. On the other hand, many consumers have less protection against high drug prices than against other types of health care costs due to differences in insurance generosity. A state primarily motivated by consumer protection concerns might decide that high-cost drugs are worth addressing even if they deliver good value.

5. How Effective Would the Massachusetts Model be in Deterring Price Hikes?

It is important to examine the incentives given manufacturers by each model. How likely would they be to keep price hikes below the allowable limit? And, would they find ways to game the system?

Because the Massachusetts model only regulates price increases in the first five years after FDA approval of a new drug, it could incentivize manufacturers to increase their launch prices for new drugs. Alternatively, manufacturers might choose to defer large price increases until the five-year period has elapsed and make up the difference with very large hikes after that time.

More generally, taxing excessive price increases may or may not deter price hikes depending on the size of the tax. It may be economically rational for companies to simply pay the tax. In the Massachusetts model, the tax constitutes only 80 percent of the excessive portion of the price increase—an amount some companies may be willing to pay. Consider the following example: if the manufacturer of Revlimid increased the price by 10 percent annually, per-patient spending in

one year would be $113,101. The allowed amount (at 2 percent above inflation) would be $106,932. The excess revenue of $6,169 exceeds the tax of $4,935 per average patient per year. In other words, the manufacturer receives $987 more per patient per year by going ahead with its planned 10 percent price hike than if it priced Revlimid at the maximum of 2 percent above inflation. Furthermore, manufacturers may determine that accepting the penalty in one state is worthwhile if few other states apply similar penalties for excessive price increases.

This example does not take into account two potential countervailing considerations. Manufacturers might think twice about violating the excessive price statute if doing so would involve (1) substantial administrative costs (for example, having to send a lot of information to the state for its price review, or making a complicated tax filing) or (2) significant adverse public-relations consequences. By increasing the "hassle factor" associated with price hikes in these ways, states could help push companies who otherwise have a moderate economic incentive to violate the statute to comply.

Another approach to the problem would be to increase the magnitude of the tax — say, from 80 to 95 percent of the excess amount. However, states walk a tightrope here when it comes to drugs that are on patent. For such drugs, the higher the tax, the more it starts to look like an attempt to usurp the patentholder's ability to reap the benefits of market exclusivity by pricing its product at whatever the market will bear. As we discuss below, this raises potential patent preemption concerns because courts have held that our federal patent scheme entitles patentholders to reap a monopoly price during the patent period.

6. What Administrative Feasibility Concerns Arise in the Two Models?

Next, we consider the administrative feasibility of identifying excessive price increases in each model. (There may be separate feasibility concerns relating to how the state collects the penalty, although the Massachusetts model does not appear problematic on that front, as it puts the burden on the company to file the tax paperwork with the commissioner of revenue.)
Both models involve labor-intensive determinations. However, states adopting the ICER model could rely on work completed by ICER that is publicly available (at no cost to states). States adopting the Massachusetts model would need to undertake the following activities:

1. **States would need to designate a state body to make determinations**, if they do not have an existing analog to Massachusetts's Health Policy Commission.
2. **To identify costly drugs, states would need access to state-level data on drug costs at the patient level**. Ideally, the data source should represent the population for which the state is eligible to claim the overpayment penalty. Depending on the proposal's reach, the state may be able to license national prescription drug audit data (e.g., from IQVIA) to obtain sales and utilization figures for their state. Alternatively, states could use all-payer claims databases. States without an all-payer claims database could request information from the largest commercial insurers in the state and/or rely on publicly available Medicare data. States would need to consider costs for data licenses and the timeliness of administrative data, which often is unavailable for one to two years from the current date. States should also consider whether the same data source would be used to determine the number of prescription fills subject to the penalty.

3. **To perform "value" assessments, states would need to have the capacity to perform cost-effectiveness analyses — or hire a third party to do so**. States could choose to define "value" in ways that do not require calculating cost-effectiveness ratios, but any sensible definition is likely to involve a weighing of the drug's clinical benefit against its cost — a fairly technical determination. The timelines specified for conducting this work should be carefully considered in light of the number of products selected for assessment, the effort involved in identifying relevant clinical and economic data, and time needed for completing the economic modeling. The value assessments will also involve outreach to manufacturers to collect information about their costs and reasons for pricing decisions and evaluate their feedback on tentative decisions. Depending on the number of drugs examined, the amount of time required could be substantial.

These administrative feasibility concerns are not trivial, but they are tractable, particularly if states share the work with outside analysts who are experienced in analyzing drug price data. Assuming there is substantial overlap in the drugs of interest across multiple states, it may be reasonable for states to share the responsibility for funding or completing value assessments, among other activities (e.g., through regional cooperatives).

Given the substantial differences in resource requirements between the two models, states may find that leveraging ICER's drug list (at no charge to states) is sufficient for meeting their goals of addressing price increases. In this case, states could apply a penalty similar to that in the Massachusetts model for the products labeled as having "unsupported price increases" in ICER's annual reports. States could also consider engaging with ICER in the drug selection process, as ICER provides an opportunity for public input regarding additional drugs of concern that should be added to its review (typically products with high per-user prices or substantial price increases that may not reach the threshold for review based on total net spending). While this approach is unlikely to capture all of the drugs of interest to states, ICER may include up to three additional products per year through to this process.

Alternatively, states may find that drugs targeted by the Massachusetts model – which include a large number of specialty drug products with very high per-user prices – are precisely those that they wish to address. If so, states could adopt a modified version of the Massachusetts model to reduce administrative burden by:

(1) Imposing minimum thresholds for total volume of prescriptions as well as minimum price per user in defining their candidate drug list; and
(2) Not conducting "value" assessments; they could instead ask manufacturers to confirm:
    (a) That their *net* price exceeded the 2 percent over inflation, and
    (b) That the price increase wasn't because of increased production or distribution costs.

Net price increases over the threshold that are not justified by higher manufacturer costs could be taxed as described in the Massachusetts model. The decisions about who violated the statute could be made by the state attorney general's office, like for other consumer protection law violations. These modifications to the Massachusetts model could reduce infrastructure demands while allowing states to pursue a broader list of products than ICER's model permits.

7. How Vulnerable Are these Models to Legal Challenges?

The models are well designed to avoid legal challenges, but states should keep three legal issues in mind as they consider making modifications to the models.
First, statutory language regarding which prices and transactions will be examined should be tailored to avoiding **dormant Commerce Clause** problems. The dormant Commerce Clause is a judicial doctrine holding that states cannot regulate in ways that place undue burdens on interstate commerce. When a state price regulation law may be applied to transactions that occur outside the state, it is potentially vulnerable to charges that it violates an aspect of the dormant Commerce Clause, called the principle of extraterritoriality, which precludes a state from regulating "commerce occurring wholly outside of its borders."[7,8,9]

The Massachusetts model is crafted to avoid this concern by explicitly limiting the penalty to in-state transactions – it specifies "a per unit penalty on all units of the drug ultimately dispensed or administered in the commonwealth." To reduce the risk of erroneously taxing drugs sold out of state, Massachusetts relies on manufacturers to specify how much they sold in-state. Although other language in the bill refers to penalizing drugs sold "directly or through another person, for distribution in the commonwealth," which could be interpreted to reach transactions between manufacturers to wholesalers that occur wholly out of state, the language limiting the penalty to drugs ultimately sold in the state eases concerns about dormant Commerce Clause claims.
To further reinforce the nexus to in-state transactions, the Massachusetts bill limits its reach to manufacturers that either maintain a place of business in the state or sell over $100,000 worth of products in the state per year. Although this could in theory exempt some manufacturers who would otherwise be penalized, it is a reasonable trade-off to avoid legal challenges. Finally, the Massachusetts model prudently examines prices paid in the state.

The ICER model, on the other hand, examines national data in selecting drugs for review. Drugs that are most costly nationally are likely to also be costly for particular states, but it would be prudent to document that fact if a state opts to work from ICER's drug lists. The ICER model does not go so far as to specify a penalty scheme, but any scheme that a state adopts should bear in mind the legal considerations that Massachusetts heeded in designing its penalty.
A second legal concern is **patent preemption**. Legal claims of patent preemption allege that a state law impermissibly intrudes into patent rights, a policy area that the Constitution reserves to the federal government.[9] Patent preemption is potentially an issue whenever a state attempts to regulate the price of on-patent products. For example, a Washington, DC (District) law prohibiting drug manufacturers from selling patented prescription drugs in the District "for an excessive price" was struck down because, the court found, "By penalizing high prices — and thus limiting the full exercise of the exclusionary power that derives from a patent — the District has chosen to rebalance the statutory framework of rewards and incentives [established by Congress] insofar as it relates to inventive new drugs."[10]

Two design features can help states avoid a similar fate when regulating excessive price increases. First, **prohibitions on excessive price increases should not apply solely to on-patent drugs**; they should also reach generic products. The court found the District's law's exclusive focus on patented drugs persuasive evidence that the District was trying to subvert the patent scheme. Second, **it is helpful to limit the magnitude of the tax**. The closer to 100

percent of the price increase the tax is, the more likely courts may see it as an attempt to deny patentholders the right to set their own price. Massachusetts's approach is conservative in taxing only the "excessive" portion of a price increase, and then only at 80 percent. Third, **if a state specifies a time period in which a tax penalty will be imposed, it should not be pegged to the period of time the drug is on patent**.

Provided these features are in place, laws regulating excessive price increases should be sufficiently distinguishable from the Washington, DC law. After all, its law regulated the *price* of the drug, not the magnitude of an allowable price *increase*. This is an important distinction because the Massachusetts model allows patent holders to establish the initial price of their products, thereby reaping monopoly returns. It simply restricts their ability to adjust the size of those returns for a limited period of time going forward. There remains an argument that among the rewards of being a monopolist is that a patent holder can raise its price if market conditions allow it. However, states are allowed considerable latitude to tax patented goods — for example, they can levy large cigarette taxes even if the higher price to the consumer means manufacturers will sell fewer cigarettes and make less money. Thus, the patent system does not guarantee the right to make the maximum possible profit on a patented product.

A third legal issue is **vagueness**. Courts have interpreted the Due Process Clause of the 14th Amendment to require states to ensure that people have fair notice of what constitutes illegal conduct and that officials enforcing the law have standards to govern their decisions.[9,11] Vagueness challenge could assert that a state's law regulating excessive price increase does not provide enough specificity as to what an "excessive" increase is, and/or fails to give adequate guidance to the decision-making body about how to evaluate price increases.

ICER's model is quite clear on these points and highly unlikely to raise such concerns. Massachusetts provides a clear definition of an excessive price, but could come under fire for its opacity around how a drug's "proposed value" will be determined. Of course, this could be set forth in administrative rulemaking. However, given the length of time required to promulgate rules, it is advisable to provide more information in the statute itself so that manufacturers cannot claim they were without guidance. Language could, for example, specify that a formal cost-effectiveness analysis will be carried out, reference accepted scientific guidelines for performing such analyses, state what constitutes an acceptable cost-effectiveness ratio, and identify other factors that the state may consider in determining a drug's overall value.

It is also advisable to specify which data sources will be used in implementing these definitions. No dataset is perfect; data sources may imprecisely represent costs to payers in the state, for example, or report those costs with a time lag. Rather than using general language such as "costs in the state," therefore, statutes could tie the term "excessive" to specific, measurable costs using particular data sources.

8. Conclusions and Recommendations

The Massachusetts and ICER models are promising models for curbing excessive prescription drug prices due to large price increases. Both models bring large price increases under scrutiny while acknowledging that when evidence shows a drug is delivering good value, high prices may

be worth paying. We offer several recommendations for states interested in these models, based on the foregoing analysis.

Selecting drugs for review:

1. Given the differences in drugs targeted between the two models, **states should first consider whether their efforts are best spent targeting drugs with the highest levels of net spending (accounting for both volume and price) or drugs that cost the most per patient**.
    a. For states that hope to address the former or that have fewer resources for conducting value assessments, using the **ICER model** to target specific products with unjustified and excessive price increases is sensible. States can leverage ICER's work, including manufacturer and stakeholder feedback and assessment of available literature to determine if price increases were potentially supported by new data. However, because ICER's assessment is national, it may not fully reflect utilization patterns in an individual state. Nevertheless, ICER's drugs represent affordability challenges for states: all seven of the products deemed as having "unsupported price increases" in ICER's 2019 report have appeared on lists of drugs with the highest total costs and/or highest total cost growth published by states. States may also nominate additional drugs through ICER's public and stakeholder input process, targeting products that represent very high per-user spending within the state but that are unlikely to be included in the top 10 drugs contributing to the highest net spending (typically, specialty drugs).
    b. If states hope to target those products with the highest per person spending and have the capacity to perform or commission the technical work required, the **Massachusetts model** is a more appropriate option. However, products meeting the specified threshold under the Massachusetts proposal are more likely to be those used for rare and complex conditions. As a result, these drugs are also likely to represent relatively low volume, which may result in a substantial work for states with limited financial return for any penalties applied for price increases.
    c. Alternatively, states could pursue a **modified Massachusetts model approach** that allows for state-specific drug selection and a broader candidate list of products than the Massachusetts proposal. This would include relaxing the $50,000-per-person threshold and eliminating or expanding the criterion relating to when the drug received FDA approval. Relaxing the five-year-post-approval requirement would have the benefit of not only expanding the law's reach, but also making it harder for manufacturers to simply delay price increases and then impose large ones. This would also make it clear that the law applies to both branded and generic products, which may help with legal challenges (described above). We would also recommend that states apply a volume threshold (e.g., minimum number of prescriptions in the state per year) to ensure that the number of products to evaluate is reasonable and effort is not focused on drugs used by a very small number of patients. States could also incorporate information regarding net drug prices (as used in the ICER model) to avoid including products whose gross sales do not reflect prices paid by the state and other payers, further reducing the list of products for assessment. Net price information could be

included in the request to manufacturers whose products have had large increases in list prices and used as the basis for defining products for which the penalty applies. States may also wish to avoid conducting "value" assessments for products, instead asking manufacturers only for specific information about their production costs that might justify a price increase. Ultimately, states must weigh the administrative burden of these drug-specific evaluations with the potential for recouping costs through the penalty.

Making determinations that price increases are excessive:

2. To avoid legal challenges based on vagueness, states should **provide clear definitions in the statute** — either by referencing the ICER protocol's definitions or describing how "excessive" price increases and a drug's "value" will be determined. The definition of "value" should be clearer than in the Massachusetts bill. Referencing cost-effectiveness analysis is an obvious strategy, but states may wish to identify additional factors that the state may consider in determining a drug's overall value.

3. **ICER's approach — examining only whether a price increase is unsupported by new evidence — is more straightforward than assessing price increase against the "value" of the drug.** States may wish to minimize administrative burden by adopting a similar assessment (asking manufacturers to inform them of new clinical data that might support their increased price) rather than attempt to conduct formal cost-effectiveness evaluations, given the time and effort needed for the latter. An additional consideration for states choosing between these approaches is that because products aren't evaluated for cost effectiveness when they first come to market, using cost-effectiveness analysis later may effectively be penalizing manufacturers for a high launch price rather than a price increase. (Suppose, for example, a drug was launched at $1,000 a month, hiked to $1,100, and the analysis determines it is only cost-effective at $800. The manufacturer would officially be taxed because of the increase, but in reality, the analysis takes aim at the launch price.)

4. **Ideally, excessive price should be evaluated using data on drug costs in the state**. If national data are used, as in ICER's work, the state should ensure and document that the list of drugs identified are also very costly drugs in that particular state. To help put manufacturers on notice of what will be examined, it is advisable to name specific data sources the state will use in making its assessments.

Structuring penalties for noncompliance:

5. **The Massachusetts approach (taxing 80 percent of the excessive portion of a price increase) is appropriate for states that wish to minimize the risk of legal challenge.** Raising the tax to closer to 100 percent of the excessive amount may be mostly more likely to trigger a patent preemption challenge, but is also more likely to deter excessive price increases.

6. To bolster incentives to comply with the statute, **states should publish an annual list of offenders** and enlist the media to help generate adverse publicity. It may also reinforce compliance to require manufacturers to submit detailed information to the state if their drug is flagged as having a potentially excessive price increase, since such submissions can require considerable time to prepare.

7. **States must apply penalties to both on-patent and generic drugs** to help avoid patent preemption claims.

8. **If a state specifies a time period in which a penalty will be imposed, it shouldn't be pegged to the time period the drug is on patent**.

9. To avoid dormant Commerce Clause problems, **states should use Massachusetts's language restricting penalties to products ultimately sold in the state** by manufacturers with a business presence in the state or minimum total sales in the state.

General considerations:

10. **If pursuing the Massachusetts model, states should hire outside experts and collaborate on the work of identifying and evaluating drugs, where possible**, to reduce administrative burden. Particularly, if cost-effectiveness analyses are contemplated, outsourcing work to analysts who are experienced performing economic evaluations and working with drug price datasets is likely to be efficient and to produce high-quality analyses for the state to review. An external evaluator may be able to work with multiple states and provide state-specific reports of drug spending and utilization. Assuming similar inclusion criteria for candidate drugs, states will likely have redundancies in drug lists, making evaluations of whether price increases are excessive relevant for multiple states.

11. Whatever model is chosen, **the law will have maximum effect if the revenue raised is earmarked for providing consumers with direct relief from high drug costs**, rather than simply absorbed into state coffers. Revenue could be devoted to providing health insurance premium subsidies, for example, or tax credits or rebates to persons with significant prescription drug expenditures in the previous year.

Notes

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[6] This analysis may be obtained from Dr. Dusetzina at s.dusetzina@vanderbilt.edu.

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