



The National Academy for State Health Policy’s Proposal for State-Based International Reference Pricing for Prescription Drugs

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Over the last few years, states have introduced and passed dozens of bills that would reduce prescription drug prices and spending, using a range of different strategies. To date, though, one potential strategy remains largely a federal initiative – the use of international reference pricing, also referred to as an international pricing index, to set an upper payment limit for purchasers. Given the large disparities in prices charged for many essential medicines in the United States as compared with many peer countries, a reference-pricing approach could result in large savings for states and their citizens. Further, many other countries have already deployed reference pricing models successfully, demonstrating their feasibility and suggesting best practices for implementation.

This brief describes the essential features of a state-based, international reference-pricing proposal, considering key design choices that would be made in its implementation and providing guidance on several potential implementation issues. This brief also articulates the key legal challenges states are likely to face in developing an international reference pricing model and recommends ways that states might design the program to minimize or avoid these legal concerns.

I. Proposal for State-Based International Reference Pricing

The core of this proposal is to enable a state to create upper payment limits on the basis of an international reference price. This brief explores three key design choices that states will face as part of this effort: the target populations, the site of the regulated transaction, and the acquisition of information. Although there are other relevant factors as well in designing these programs, each of these choices affects not only the scope and impact of the reference pricing program, but also the set of potential legal challenges (articulated in Part II) that are likely to be brought against it.

1. Identifying the Target Populations

In developing a proposed international reference pricing program, a state must choose its target populations. First and most obviously, states may seek to apply this program to the prescription drugs purchased by a variety of state actors. States serve as both purchasers of and payers for prescription drugs for a wide range of populations, perhaps most notably for Medicaid beneficiaries, public employees, and people who may be incarcerated. Adopting a reference-pricing approach within these populations would permit states to lower their own spending on prescription drugs, and in the case of public employees, would provide the opportunity to lower patients’ out-of-pocket costs as well.¹

Second, states may also seek to extend this program to private purchasers or payers. States have a direct financial interest in the prices obtained by these insurance plans, most obviously through the state tax exclusions provided to employer sponsored coverage and tax-deductibility of coverage that individuals may choose to purchase, but also through the increased burdens that high prescription drug prices place on a large number of Americans.² As such, states may seek to extend the benefits of an international reference pricing system to private payers, on behalf of their citizens. States are within their rights to extend these benefits to non-ERISA plans operating within the state but will face substantial legal difficulties in mandating that these benefits be extended to self-funded ERISA plans. However, states would be on firmer ground making an international reference pricing program available to ERISA plans on an opt-in basis. Applying reference pricing to these populations would also permit private payers to lower patients' out-of-pocket costs.

2. Choosing the Site of the Regulated Transaction

States seeking to implement an international reference pricing program must also articulate where the program is to be implemented. In other words, which of the many transactions along the complex prescription drug supply chain is to be benchmarked to the international price in question? The core of the international reference-pricing approach is that it sets the maximum price that the insurer is willing to pay for the relevant prescription drug. It imposes no restriction on pharmaceutical companies' ability to charge prices that exceed the reference pricing benchmark, but merely does not force payers to accept that price and does not guarantee that companies will find a willing buyer at the price of their choosing. As such, the clearest way to conceive of the regulated transaction would be to target the purchase of the product by the insurer in question. Under this approach, the law in question provides that the purchaser or payer will not provide reimbursement for the drug in question at a price that exceeds the maximum benchmarked price, whether the purchase is from the manufacturer or a wholesaler. Alternatively, states might also choose to regulate the terms of the sale of prescription drugs from the manufacturer or wholesaler to the retail pharmacy located in the state and/or the transaction in which the in-state consumer is dispensed the drug by a retail pharmacy. However, this latter approach may constrain states' ability to apply a reference-pricing approach to physician-administered drugs.

3. Obtaining the Relevant Pricing Information

In order to implement an international reference pricing system, states must be in a position to gather the relevant international pricing information needed to set the benchmark price. In theory, states could compel manufacturers to disclose the relevant international prices per unit of the relevant drug products, or face civil fines for a lack of compliance. But obtaining the information directly from the manufacturers not only would likely lead to litigation seeking to invalidate the legislation on trade secrecy grounds, but also would require states to invest in efforts to ensure compliance with the reporting requirements and to enforce those requirements. Instead, states can more easily obtain the information from various available data sources.

One commonly used data source is IQVIA's database on international sales and volume, referred to as MIDAS.³ MIDAS contains information about drug prices from nearly 100 countries,⁴ and

interested states might purchase a license to MIDAS' data, as federal government entities have done.⁵ Instead, though, states might seek to use publicly available data from countries that may be included in the reference pricing basket. For example, the United Kingdom's Drug Tariff lists its National Health Service's reimbursement rate for prescription drugs and would be one potential source.⁶ As another option, states might seek to reference their prices against those of just one country, as long as that other country uses international reference pricing as a primary tool to control its prescription drug prices. A clear candidate might be Canada, which considers the prices charged for a drug in question in a set of other, comparable markets in determining whether a drug's price is excessive.⁷ States ought to be cognizant of the fact that these data sources may not be complete, however, and may not reflect additional country-specific discounts that could be held as trade secrets.

Within the United States, if either the Trump Administration's Medicare Part B International Pricing Index Model or the international reference price negotiation elements of the Elijah Cummings Lower Drug Costs Now Act becomes law (as described in more detail in Part III), states could reference those prices in setting their own upper payment limits.

II. Potential Legal Issues for State-Based International Reference Pricing Programs

Setting an upper payment limit on the basis of an international reference price raises a number of legal questions, regardless of which design choices a state elects. However, states can minimize or avoid these legal barriers through careful design of the relevant program. States should expect at least four legal hurdles to arise: preemption challenges arising under the patent statute, dormant commerce clause challenges, Medicaid barriers, and Employee Retirement Income Security Act of 1974 (ERISA) arguments.

1. Federal Preemption Concerns Relating to the Patent Statute

A state seeking to implement an upper payment limit through international reference pricing can anticipate that manufacturers of patented drugs will argue that the state's setting of the upper payment limit is preempted by federal patent law.⁸ Specifically, manufacturers will rely on *Biotechnology Industry Organization v. District of Columbia*,⁹ in which the US Court of Appeals for the Federal Circuit invalidated on conflict preemption grounds¹⁰ a Washington, DC law preventing "patented prescription drug[s]" from being sold in Washington, DC "for an excessive price."¹¹ The statute further provided that a prima facie case of excessive pricing "shall be established where the wholesale price of a patented prescription drug" sold in Washington, DC is "30 percent higher than the comparable price" in the United Kingdom, Germany, Canada, or Australia.¹²

Trade associations representing both biotechnology and pharmaceutical firms challenged the law's constitutionality on several grounds, most importantly federal preemption. The associations contended that the law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of"¹³ the federal patent law and therefore ought to be struck down under the law of conflict preemption.¹⁴ The Federal Circuit agreed, concluding that the law's specific focus on patented drugs functioned to "penaliz[e] high prices" and "limit[] the full exercise of the exclusionary power that derives from a patent."¹⁵

State upper payment limits and the use of international reference pricing should not, however, trigger such preemption concerns for at least two reasons.

- First, legislative drafters should not limit their efforts to patented products alone. States may consider many other ways of selecting products for inclusion in a reference pricing system, but would be on strong legal ground if they avoided specifying patented products only. The Federal Circuit noted that states have broad, general police powers, and patent rights can be subordinated to the general exercise of state power. It was the specific, sole focus on patented products which proved fatal for the Washington, DC law.¹⁶
- Second, unlike the Washington, DC law, NASHP’s proposed legislation would not regulate the price a manufacturer is able to charge for a product. It would instead regulate the *purchase* of the product, setting the maximum price at which a payer is willing to provide reimbursement. The law would impose no limit on pharmaceutical companies’ ability to charge prices that exceed the reference pricing benchmark, but simply does not force payers to accept that price.

2. Dormant Commerce Clause Issues

States would likely also face dormant Commerce Clause (DCC) challenges to any upper payment limit system.¹⁷ Manufacturers would argue that the practice of setting a maximum price for drugs purchased by state or non-state payers is “designed to benefit in-state economic interests by burdening out-of-state competitors,”¹⁸ and therefore would fail under the DCC. Manufacturers would point specifically to *Association for Accessible Medicines (AAM) v. Frosh*,¹⁹ in which the United States Court of Appeals for the Fourth Circuit invalidated Maryland’s law prohibiting “price gouging in the sale of an essential off-patent generic drug”²⁰ because “it directly regulates transactions that take place *outside Maryland*.”²¹

AAM has not been without controversy. The Fourth Circuit invalidated Maryland’s law over a strong dissent arguing that the statute requires an in-state sale for its applicability.²² Further, there has been extensive scholarly criticism of the opinion’s legal analysis, meaning that states residing within other circuits might reasonably believe that the courts reviewing the constitutionality of an international reference pricing proposal might reach a different decision. However, it is also likely that *AAM* has served as a deterrent for other states interested in drug pricing reform, and that states should take additional steps to limit the potential impact of a DCC challenge.

States aiming to impose an upper payment limit would be on stronger legal ground if they explicitly limited the application of their program to in-state transactions, where the DCC has less applicability. The court in *AAM* specifically pointed to the Maryland law’s applicability to drugs “*made available for sale*” (emphasis added) rather than *actually sold* in Maryland as allowing Maryland to “enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland”²³ — in other words, burdening out-of-state transactions. The court distinguished other cases in which it had upheld similar statutes focused specifically on in-state transactions against DCC challenges.²⁴

Manufacturers would still likely challenge a statute focused explicitly on in-state transactions, arguing that regulating the prices in-state payers pay manufacturers or wholesalers even for in-state transactions would by necessity be targeting sales “upstream from consumer retail sale” that will “occur almost exclusively outside the state.”²⁵ This argument is driven by the complexity of the prescription drug supply chain. In other words, one argument could be that the manufacturer or wholesaler does not truly sell prescription drugs to the in-state payer itself, but instead sells the drugs to the pharmacy which then dispenses drugs to the patient under terms determined by the payer’s pharmacy benefit manager (PBM), on behalf of the payer. The PBM may be based in another state, and its negotiation with the manufacturer or wholesaler over prices may also occur out-of-state. As such, a manufacturer could argue that regulating a transaction between the manufacturer or wholesaler and payer nevertheless involves an out-of-state transaction.²⁶

As such, states seeking to implement an upper pricing limit through international reference pricing would be on even stronger legal grounds if they also regulated the terms of the sale of prescription drugs from the manufacturer or wholesaler to the retail pharmacy located in the state and/or the transaction where an in-state consumer is dispensed the drug by a retail pharmacy. These transactions would clearly be in-state transactions subject to the regulatory authority of the state, which has broad power to regulate pharmacy conduct. However, as noted above this approach may limit states’ ability to apply a reference pricing framework to drugs administered by physicians.

States might also expect manufacturers to raise another commerce clause issue in opposition to a state reference pricing system: the dormant foreign commerce clause. Specifically, states are limited in their ability to pass laws that apply to foreign commerce, because those laws have the potential to “frustrate the achievement of federal uniformity.”²⁷ The relevant trade associations might well argue that a state reference pricing system would be unconstitutional under the foreign commerce clause.

However, the Supreme Court to date has applied the foreign commerce clause primarily in highly limited situations involving double taxation (by the states in addition to the federal government). Where there is an “enhanced risk of multiple taxation,”²⁸ the court is particularly concerned that the federal government is able to “speak with one voice when regulating commercial relations with foreign governments.”²⁹ In general, states are free to engage in commerce with foreign state actors in a wide range of areas.³⁰ As the law in question here would not implicate double taxation issues, this is comparatively less likely to be a serious concern for states.

3. Medicaid Barriers

An additional set of legal complications arise in the context of state Medicaid plans. Seeking to implement upper payment limits through state Medicaid plans has both advantages and disadvantages relative to implementing these limits through other insured populations (including other state-funded populations, such as state employees). State Medicaid programs choosing to provide coverage for prescription drugs must cover essentially all US Food and Drug Administration- (FDA) approved drugs.³¹ Yet because these coverage requirements place a great deal of bargaining power in the hands of pharmaceutical companies to set their own prices, these

coverage requirements come with preferred pricing benefits for states. States are entitled to obtain large statutory rebates off of a drug's Average Manufacturer Price, and if the company in question offers even larger discounts to other private payers, Medicaid is entitled by law to that "best price" provided to another entity.³²

First, due to these coverage requirements and terms, a state aiming to implement international reference pricing through its Medicaid program would need to obtain approval from the Centers for Medicare & Medicaid Services (CMS) to do so. Under some versions of an international reference pricing approach, this approval would likely be easily granted. For instance, if the state sought only to use an international reference price as a trigger for close scrutiny and examination of the drug's price, intending to result in a supplemental rebate agreement, the state might only need to submit a state plan amendment (SPA). This would likely be approved easily, as it resembles the innovative payment models other states have adopted to seek supplemental rebates.³³

But if the state sought to impose an upper payment limit in its Medicaid program, the state would likely need to submit an 1115 waiver, asking CMS to waive the requirement that states cover essentially all FDA-approved drugs as it relates to the class of drugs for which states seek to apply this upper payment limit (as discussed below, in Part III.3). More specifically, the state would request that CMS permit it to decline to cover certain drugs in order to achieve greater bargaining authority with recalcitrant manufacturers who do not want to adhere to the international pricing index limit, while also retaining at least the mandatory minimum Medicaid rebates.

Such a request is within CMS' authority to grant. Section 1115 of the Social Security Act permits CMS to waive compliance with "any of the requirements of section ... 1902" of the Act to enable states to engage in "any experimental, pilot, or demonstration project which ... is likely to assist in promoting the objectives of" the Act.³⁴ One of the requirements of section 1902 is for states to "comply with the applicable requirements of section 1927," which governs the provision of Medicaid funding for outpatient prescription drugs.³⁵ States may seek to waive that requirement, as it incorporates section 1927, enabling them to decline to cover essentially all approved drugs while also retaining the mandatory minimum rebates.

CMS' authority to grant these waivers is not without controversy from the agency's perspective. As recently as 2018, CMS had declined to approve an 1115 waiver from Massachusetts that made this request (although not for international pricing index reasons).³⁶ Importantly, though, in rejecting Massachusetts' request, CMS did not claim that it lacked the legal authority to grant such a waiver. Subsequently, in January 2020, in articulating to states how they might pursue a Medicaid block grant program with CMS, CMS explained that it would be willing to permit states to engage in just this practice — decline to cover certain drugs but retain the mandatory minimum Medicaid rebates.³⁷ Although CMS has claimed that these waivers are only obtainable within the context of the block grant program,³⁸ there is no clear legal reason why that should be the case. In other words, the relevant statutory section can be waived independently of a block grant program.

A related set of concerns involves the Medicaid best-price requirement. States seeking to use international reference pricing for their state employees, correctional populations, or in other groups of beneficiaries might find that the international reference price would trigger the manufacturer's best-price obligations in the Medicaid program, depending on the Medicaid price as compared to the target international price. If so, a manufacturer that agreed to sell its product at the internationally benchmarked price to a state employee plan might then need to offer that price to all state Medicaid programs nationwide. In some cases (such as for products with high Medicaid market share), states might be concerned about a manufacturer's willingness to walk away from their market (as discussed below, in Part III.4), and they might provide a fallback price of a state's mandated Medicaid rebate adjusted for the relevant inflationary penalty³⁹ as an alternative.

A state implementing an international pricing index in the Medicaid context under either of the above situations should seek to do so through a supplemental rebate agreement model. Such an agreement would enable a state to achieve a lower price for a particular product without fear of triggering Medicaid best-price obligations in other states.⁴⁰

4. ERISA Preemption Challenges

As noted above, states seeking not only to establish an upper payment limit but also to extend it to private ERISA plans should consider doing so on an opt-in basis. Because states' ability to regulate private health insurance is limited in the context of self-funded insurance plans,⁴¹ requiring ERISA plans to adopt the international reference-pricing approach would likely lead to ERISA preemption challenges. These challenges would not apply to the state's establishment of the limit in the context of public programs or private, non-ERISA plans, but the large size of the patient population receiving insurance through ERISA plans makes this a potentially concerning limitation for states in their ability to extend the benefits of such a program to many of their citizens.

To be sure, the effect of a successful ERISA preemption challenge would be to exclude self-funded ERISA plans from the scope of the state law, rather than to invalidate the law wholesale. Further, it is possible that ERISA plan sponsors would not even seek to challenge the law, if it enables them to obtain better prices than they would otherwise be able to obtain.⁴² But as states draft these bills, they should therefore consider 1) extending upper payment limits to ERISA plans on an opt-in basis, 2) clearly separating out the provisions of the law relating to public and private payers, and 3) including an explicit severability clause providing that the invalidation of any provision of the law would not affect the remaining portions of the statute.

III. Implementing State-Based International Reference Pricing

States seeking to adopt an upper payment limit through international reference pricing face a number of additional implementation choices. Although this brief cannot provide an analysis of every such issue, five are likely to be of particular interest to states: which countries to include as reference points, the target price to be paid, which drugs to include in the program, what

remedies to impose on manufacturers who resist the structure, and how to ensure cost savings accrue to patients as well as plans.

Several of these practical implementation choices are likely to require states to bring to bear expert advice and opinions. Particularly as states must identify applicable countries, develop pricing data, and evaluate the set of drugs to which to apply the reference pricing framework, being able to call on experts to evaluate and provide guidance on these issues will be key to their implementation. In many instances, states may be able to make high-level political decisions (such as regarding which countries to include in the framework) and devolve operational issues to insurers, pharmacy benefit managers, or other actors within the system. Organizations like NASHP may be able to provide additional convening structures to support states in their efforts.

Initially, states might look to at least two examples of recent proposals for international reference pricing at the federal level for inspiration as to the answers to these questions. First, in October 2018, the Trump Administration introduced an advance notice of proposed rulemaking (ANPRM) that, if finalized, would implement an international reference pricing proposal for prescription drugs reimbursed through Medicare Part B.⁴³ In essence, the amount Medicare reimburses a set of private sector vendors for Part B drugs would be tied to an international reference price, with the goal of reducing Part B spending by 30 percent.⁴⁴ As of mid-April 2020, however, the administration has not yet moved forward with the proposal.

Second, in December 2019, the House of Representatives passed H.R. 3, the Elijah Cummings Lower Drug Costs Now Act.⁴⁵ One of the act's three pillars⁴⁶ provides the Secretary of Health and Human Services (HHS) with the authority to negotiate the price of prescription drugs, and the Act creates an international pricing index to be used as a target price ceiling in those negotiations.⁴⁷

1. Applicable Countries for Reference Pricing

Any state seeking to adopt an international reference pricing program must choose the basket of international prices to use as a benchmark. The Trump administration's ANPRM considered using pricing data from 16 countries: Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, and the United Kingdom.⁴⁸ H.R. 3 selected just six countries to target: Australia, Canada, France, Germany, Japan, and the United Kingdom.⁴⁹ Many other countries around the world also use international reference pricing as part of their process for determining reimbursement rates for prescription drugs, but they have all selected different sets of countries to target.⁵⁰

As states select countries to include in their basket, they might be attentive to several factors used by other countries as they select their own comparator countries. Many regulators select countries for inclusion which have comparable gross domestic product (GDP) levels or similar economic conditions.⁵¹ Ethical considerations suggest that states should similarly include only countries with comparable GDPs within their reference-pricing basket, following both the Trump Administration and the Democratic majority in the House of Representatives. Including countries with much lower GDPs within the benchmarking analysis could jeopardize the access to

essential medicines of citizens of those countries, whose leaders may have fewer resources to bring to bear on the problem.

From a more practical perspective, regulators might also seek to include countries where existing, accessible data sources contain pricing information.⁵² Particularly if states are concerned about the possible trade secrecy concerns as above, data availability may be a salient factor to consider. There is no one answer to the particular countries states should include, but administrability and comparability are certainly relevant issues.

States must also consider a range of practical questions related to the selection of countries. For instance, determining how often to update the relevant reference prices and considering how to deal with new products that may enter the US market⁵³ but lack sufficient comparable international data to select a relevant reference price. H.R. 3 explicitly considered the possibility that an international pricing index could not yet be calculated for a drug subject to negotiation and required future rebates from manufacturers if the US price exceeds 200 percent of the later-available international price.⁵⁴

2. Identifying a Target Price

States must select not only which countries to use as international reference targets, but also how they will seek to benchmark their own prices as against those other countries. For instance, H.R. 3 uses its international reference-pricing approach to set a price ceiling: the HHS Secretary is not permitted to accept a negotiated price that exceeds 1.2-times the volume-weighted average of the drug's price in the relevant countries. Other countries in their reference-pricing models may use the lowest price in their reference basket, or the mean or median.⁵⁵

States seeking to apply reference pricing to in-state, non-Medicaid public programs or to private non-ERISA plans should be aware that doing so may have a range of effects beyond the reference pricing upper payment limit itself. As noted in Part II.3 above, the choice of a reference price might impact the calculation of a Medicaid best price.

3. Selecting Drugs for Program Inclusion

States must also decide which drugs will be candidates for inclusion in their reference-pricing programs. There is a broad range of possibilities that states may consider in answering this question. States may decide that any drug purchased in a relevant, in-state transaction should be subjected to an upper payment limit, hewing more closely to the approach taken by the Trump Administration in its ANPRM and suggesting that any Medicare Part B products ought to be subject to their international pricing index.

Other states may opt to restrict the reach of the reference-pricing approach only to the drugs that are the most costly to public payers or have particular public salience (such as insulin). This approach would more closely resemble the decision of House Democrats to instruct the HHS Secretary to engage in a time-intensive negotiation process involving an international pricing index but limiting that inquiry to a particularly costly set of 250 drugs.⁵⁶

Another approach would use international reference pricing for drugs whose manufacturers raise their prices beyond a specified amount in a particular time frame. H.R. 3 requires manufacturers who raise the relevant prices of their drugs sold in Medicare Part B or Part D more rapidly than inflation to either lower their prices or repay the additional amount above inflation back to the federal government in the form of a rebate.⁵⁷ The drug pricing package approved by the Senate Finance Committee, under the leadership of Chairman Chuck Grassley and Ranking Member Ron Wyden, similarly includes a penalty for price increases outpacing inflation in both Part B and Part D.⁵⁸ Here, states might use such price increases as a trigger for international reference pricing.

Most importantly, any criteria that states articulate for selecting a set of drugs for program inclusion should be phrased generally. The Washington, DC price-setting law that was struck down on conflict preemption grounds, as discussed above, encountered legal trouble precisely because it specifically targeted patented products. A statute that applied broadly would be less likely to face such trouble.

4. Remedies for Manufacturer Noncompliance

States can expect that pharmaceutical manufacturers will be resistant to the setting of the upper payment limit, and may seek to find ways to prevent its imposition (including lobbying against the passage of the legislation and bringing legal challenges grounded in some or all of the above theories). But even once such a law is enacted, manufacturers may threaten to refuse to sell some or all of their drugs in states with such payment limits. To be sure, manufacturers are in fact willing to sell their products at the relevant prices in other countries, and they do earn profits at those prices.⁵⁹ As such, it is unlikely that any company would follow through on such a threat, but they might well make it.⁶⁰

In response to such concerns, states can take a number of actions. First, states might take a lesson from the House Democrats' bill (as described above) and assess a civil penalty for firms which refuse to comply with the upper payment limit.⁶¹ Second, at least some states may have consumer protection laws which could form the basis of a lawsuit against a recalcitrant manufacturer, with the state arguing that setting US-based prices many times higher than the prices charged in other countries may constitute an unfair trade practice.⁶² Third and relatedly, states might seek creative antitrust remedies against manufacturers who refuse to deal with them on the same terms they deal with foreign payers. Fourth, states might encourage the federal government to take various types of actions relating to manufacturer noncompliance, including everything from oversight and investigations to patent review and compulsory licensing.⁶³

5. Ensuring Benefits Accrue to Patients

State programs that seek to lower the costs of prescription drugs must seek to lower patients' out of pocket costs, in addition to decreasing state or private payer spending, as today far too many patients experience difficulty affording their medications.⁶⁴ The savings accruing from an international reference pricing program should be passed along to patients where legally feasible. This might most usefully be done through premiums, copays, or a combination of the two. That is, one approach would require payers to share their savings with patients and spread those

savings out by lowering premiums for all beneficiaries. Payers might separately seek to pass through savings to the beneficiaries consuming the products with the largest cost savings, so that their pharmaceutical costs are reduced accordingly. These benefits would be less impactful for those whose out-of-pocket costs are tightly controlled by law, such as Medicaid beneficiaries.⁶⁵

IV. Summary of Recommendations for State Policymakers

States seeking to implement an international reference pricing program will undoubtedly face both administrative and legal challenges in doing so, but the potential benefits for patient access and for drug pricing and spending are potentially very large. State policymakers ought to consider the following recommendations as they design and implement these programs.

Design Recommendations for State-Based International Reference-Pricing Approaches

Which populations should be included?	<ul style="list-style-type: none"> • Option 1: Citizens covered by publicly provided insurance, including public employees • Option 2: State Medicaid populations, including people who may be incarcerated if organized as a 340B facility • Option 3: Citizens covered by private non-ERISA plans, permit ERISA plans to opt in
Which transaction should be regulated?	<ul style="list-style-type: none"> • Option 1: Those that are purchased within the state by regulated payers • Option 2: In-state sales involving retail pharmacy facilities
How should pricing data be obtained?	<ul style="list-style-type: none"> • MIDAS • If not feasible, publicly available databases including the UK’s Drug Tariff lists. (Note: this choice would limit states’ decisions regarding countries to include in their reference-pricing comparisons.)
Which countries should be included in the reference pricing basket?	<ul style="list-style-type: none"> • Countries with comparable GDPs • Countries whose pricing information is more readily obtainable • Keeping the sample size small (closer to H.R. 3’s list of six than the Trump Administration’s list of sixteen) may help mitigate administrative burdens
How should a target price be identified?	<ul style="list-style-type: none"> • Articulate budgetary limitations and set of products to include in the program

	<ul style="list-style-type: none"> Consider potential impacts on payers or products outside the program (such as the Medicaid best price, if applicable)
Which products should be included in the reference pricing program?	<ul style="list-style-type: none"> Option 1 (preferred): Any drug subject to a relevant in-state transaction, whether or not it is covered by patents or other regulatory exclusivities Option 2: A more limited set of drugs which are the most costly for the relevant payers Option 3: Drugs whose manufacturers engage in price increases beyond a certain, specified threshold In any of these situations, the statute should not be limited to patented products only.
Other	<ul style="list-style-type: none"> Consider including civil penalties or fines to strengthen the state’s ability to respond to threatened manufacturer noncompliance. Ensure benefits are passed through to patients, rather than accruing entirely to payers.

Notes

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¹ This consideration is less applicable in other contexts involving public payers. For instance, Medicaid beneficiaries’ out-of-pocket obligations are sharply limited, by law. See 42 C.F.R. § 447.56 (2014) (exempting large classes of Medicaid beneficiaries from cost-sharing under the program); 42 C.F.R. § 447.53(b) (2013) (limiting out-of-pocket payments for other Medicaid beneficiaries).

² Rabah Kamal et al., *What Are the Recent and Forecasted Trends in Prescription Drug Spending?*, PETERSON-KAISER HEALTH SYSTEM TRACKER (Dec. 10, 2018), <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/>.

³ IQVIA, MIDAS (2020), <https://www.iqvia.com/solutions/commercialization/brand-strategy-and-management/market-measurement/midas>.

⁴ *Id.*

⁵ U.S. Dep’t of Health & Human Servs., Office of the Assistant Sec’y for Planning & Evaluation, *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures*, at 4 (Oct. 25, 2018), <https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>.

⁶ National Health Service, *Drug Tariff* (April 2020), <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff>.

⁷ Health Canada, *Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations*, at 6 (2017), <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-regulations-patented-medicine-document/con1-eng.pdf>.

⁸ By necessity, I provide only a brief treatment of this issue here. A complete paper on this topic has been written separately. See Robin Feldman et al., *States' Rights: A Patent Law Analysis of NASHP Rate-Setting Model Act* (March 2018), <https://nashp.org/wp-content/uploads/2018/03/White-Paper-2018.pdf>.

⁹ 496 F.3d 1362 (Fed. Cir. 2007).

¹⁰ *Id.* at 1365, 1374.

¹¹ D.C. Code § 28-4553.

¹² D.C. Code § 28-4554(a).

¹³ See *Biotechnology Industry Organization*, 496 F.3d at 1372 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

¹⁴ *Id.* at 1372.

¹⁵ *Id.* at 1374.

¹⁶ *Id.* at 1373–74; *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1348 (Fed. Cir. 2007) (Gajarsa, J., concurring in the denial of rehearing en banc); see also Feldman et al., *supra* note 8, at 4.

¹⁷ Anna Zaret & Darien Shanske, *The Dormant Commerce Clause: What Impact Does It Have on the Regulation of Pharmaceutical Costs?* (Nov. 2017), https://nashp.org/wp-content/uploads/2019/02/DCC-White-Paper-new-version-wi-CK-edits-2_14_2019.pdf.

¹⁸ *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (quoting *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273–274, (1988)).

¹⁹ 887 F.3d 664 (4th Cir. 2018).

²⁰ *Id.* at 666; see also Md. Code Ann. § 2-802(a).

²¹ *Association for Accessible Medicines*, 887 F.3d at 674.

²² *Id.* at 678–79 (Wynn, J., dissenting).

²³ *Id.* at 671.

²⁴ *Id.* at 670–71.

²⁵ *Id.* at 671.

²⁶ The 4th Circuit concluded that the Maryland law regulated the initial sale price for a drug charged by a manufacturer or wholesaler/distributor, which would be an impermissible state regulation of a wholly extraterritorial transaction even if it only applied to drugs that ultimately were sold in Maryland. *Id.* at 671.

²⁷ *Japan Line, Ltd. v. Los Angeles Cty.*, 441 U.S. 434, 450 (1979).

²⁸ *Id.* at 446.

²⁹ *Michelin Tire Corp. v. Wages*, 423 U.S. 276, 285 (1976).

³⁰ Duncan B. Hollis, *Unpacking the Compact Clause*, 88 TEX. L. REV. 741, 744 (2010).

³¹ 42 U.S.C. § 1396r-8(k)(2) (2012).

³² *Id.* § 1396r-8(c)(1)(A)(ii)(I). There are certain statutory exclusions from this calculation, such as prices paid by Medicare Part D plans. See *id.* § 1396r-8(c)(1)(C)(i).

³³ See, e.g., Ctrs. for Medicare & Medicaid Servs., *CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers* (June 27, 2018) (approving Oklahoma's use of outcomes-based contracts in the service of supplemental rebate agreements), <https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicare-value-based-arrangements-drug-makers>; Ctrs. for Medicare & Medicaid Servs., *CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid* (June 26, 2019) (approving Louisiana's use of a subscription model in the service of supplemental rebate agreements), <https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified>.

³⁴ See Ctrs. for Medicare & Medicaid Servs., *About Section 1115 Demonstrations*, MEDICAID.GOV (last visited April 18, 2020), <https://www.medicare.gov/medicaid/section-1115-demo/about-1115/index.html>; 42 U.S.C. § 1315(a)(1) (2012).

³⁵ Social Security Act § 1902(a)(54); 42 U.S.C. § 1396a(54) (2012).

³⁶ Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 NEW ENG. J. MED. 1002, 1002 (2018).

³⁷ Centers for Medicare and Medicaid Servs., *Dear State Medicaid Director: Healthy Adult Opportunity Program* at 9 (Jan. 30, 2020), <https://www.medicare.gov/sites/default/files/Federal-Policy-Guidance/Downloads/smd20001.pdf>.

³⁸ Sarah Owerhohle & Sarah Karlin-Smith, *Drugmakers Blast Medicaid Block Grants*, POLITICO (Jan. 31, 2020), <https://www.politico.com/newsletters/prescription-pulse/2020/01/31/drugmakers-blast-medicare-block-grants-784910>.

³⁹ Medicaid is insulated from price increases in existing drugs that outpace the inflation rate. 42 U.S.C. § 1396r-8(c)(2)(A) (2012). More than half of Medicaid rebates have been estimated to be due to these protections. Dep't of

Health & Human Servs., Office of Inspector Gen., OEI-03-13-00650, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin 8 (2015).

⁴⁰ 42 C.F.R. § 447.505(c)(7) (2016).

⁴¹ Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. Penn. L. Rev. 389, 420–21 (2020).

⁴² However, PBMs for ERISA plans who operate under certain types of revenue structures may feel that challenging the law is in their financial interest.

⁴³ Rachel Sachs, *Administration Outlines Plan to Lower Pharmaceutical Prices in Medicare Part B*, HEALTH AFF. (Oct. 26, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full>; Ctrs. for Medicare & Medicaid Servs., *International Pricing Index Model for Medicare Part B Drugs*, 83 Fed. Reg. 54,546 (Oct. 30, 2018).

⁴⁴ Ctrs. for Medicare & Medicaid Servs., *International Pricing Index (IPI) Model* (2018), <https://innovation.cms.gov/innovation-models/ipi-model>.

⁴⁵ Elijah E. Cummings Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong. (2019).

⁴⁶ Rachel Sachs, *Understanding the House Democrats' Drug Pricing Package*, HEALTH AFF. (Sept. 19, 2019), <https://www.healthaffairs.org/doi/10.1377/hblog20190919.459441/full>.

⁴⁷ Elijah E. Cummings Lower Drug Costs Now Act of 2019, at § 101.

⁴⁸ 83 Fed. Reg. at 54,550.

⁴⁹ Elijah E. Cummings Lower Drug Costs Now Act of 2019, at § 101.

⁵⁰ Panos Kanavos et al., *Does External Reference Pricing Deliver What it Promises? Evidence on Its Impact at National Level*, 21 EUROPEAN J. HEALTH ECON. 129, 136 (2020).

⁵¹ *Id.* at 129, 83 Fed. Reg. at 54,557.

⁵² 83 Fed. Reg. at 54,557.

⁵³ Nicholas S. Downing et al., *Regulatory Review of New Therapeutic Agents – FDA Versus EMA, 2011–2015*, 376 N. ENG. J. MED. 1386, 1386 (2017) (concluding that the FDA approves products more quickly than does its peer agency in Europe).

⁵⁴ Elijah E. Cummings Lower Drug Costs Now Act of 2019, at § 101.

⁵⁵ Kanavos et al., *supra* note 50, at 144.

⁵⁶ Elijah E. Cummings Lower Drug Costs Now Act of 2019, at § 101.

⁵⁷ *Id.* at § 201, 202.

⁵⁸ Prescription Drug Pricing Reduction Act of 2019, S. 2543, 116th Cong., at § 106, 128 (2019).

⁵⁹ *Drug Pricing in America: A Prescription for Change, Part II, Hearing before the Comm. On Finance, U.S. Senate*, 116th Cong., at 20 (Feb. 26, 2019), <https://www.finance.senate.gov/imo/media/doc/37143.pdf>.

⁶⁰ To be sure, there are isolated cases in which manufacturers have followed through on threats to make their drugs unavailable in certain international markets, where the governments in question were only willing to pay a price lower than what the manufacturer would accept. Perhaps Vertex's dispute with the National Health Service in the UK over reimbursement for its newest cystic fibrosis products is the most prominent example. However, in other ways the notoriety of these exceptions may prove the rule: in the vast majority of cases, companies do accept health insurers' offers and make their products available for sale. Indeed, Vertex ultimately reached a deal with the NHS to make its products available. Denise Roland, *Vertex Resolves Yearslong Drug-Price Dispute in England*, WALL ST. J. (Oct. 24, 2019), <https://www.wsj.com/articles/vertex-resolves-yearslong-drug-price-dispute-in-england-11571928563>.

⁶¹ H.R. 3 envisions that drug manufacturers who refuse to negotiate or fail to reach an agreement with HHS will be assessed a high Non-Compliance Fee, starting at 65 percent of the gross sales of the drug in question in the previous year and increasing by 10 percent every quarter, to a maximum of 95 percent. Elijah E. Cummings Lower Drug Costs Now Act of 2019, at § 102.

⁶² Massachusetts Office of the Attorney General, *Letter to John C. Martin, Chairman and Chief Executive Officer of Gilead Sciences* (Jan. 22, 2016), <http://freepdfhosting.com/4a608bcd36.pdf>.

⁶³ See Amy Kapczynski & Aaron S. Kesselheim, "Government Patent Use": *A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFAIRS 791 (2016) (proposing the use of 28 U.S.C. § 1498 to lower prices for high-cost drugs).

⁶⁴ Kamal et al., *supra* note 2.

⁶⁵ See, e.g., 42 C.F.R. § 447.53(b) (2013) (providing that individuals with family income less than or equal to 150% of the federal poverty line may not be charged more than \$4 in cost-sharing for preferred drugs or \$8 for non-preferred drugs, inflation-adjusted).