



NASHP's Proposal for State-Based Prescription Drug Affordability Boards

Rachel E. Sachs*

Several states have recently expressed interest in the use of Prescription Drug Affordability Boards (PDABs) in an effort to reduce prescription drug prices for both patients and payers. PDABs may be created to have a range of functions, including but not limited to identifying particular high-priced drugs, obtaining affordability reviews for a selected set of those products, and establishing upper payment limits for certain payers, depending on the results of the affordability reviews.

This brief has two main goals. First, it describes several key design choices states would need to make in shaping their PDABs and provides guidance on the range of options states have as they make those choices. Second, it identifies several legal challenges states may face in developing and implementing PDABs, suggesting opportunities for states to design their Boards to minimize or avoid legal concerns.

In these analyses, this brief draws on states' previous experiences with a range of drug pricing reform legislation. From a legal perspective, several factors differentiate proposed PDAB legislation from often-discussed previous efforts. For instance, PDABs do not control the prices manufacturers can charge for their products, but instead alter the prices payers are willing to pay for those same products. PDABs focus on in-state sales and in-state patients, limiting their scope. And they build on a wealth of information that has been developed about how to conduct affordability reviews and establish payment limits.

I. Design Choices in Implementing State-Based Prescription Drug Affordability Boards

This brief identifies and analyzes four design choices states will face in implementing PDABs: the selection of products for inclusion and analysis, factors to consider in operationalizing both an affordability review and upper payment limit establishment, potential appellate issues, and remedies for noncompliance. To be sure, states may face a range of additional design choices as well, some of which may be state-specific in nature. This brief focuses on these four choices both because they affect the impact of the PDABs and also because they shape the potential legal challenges (identified in Part II) which may be brought.

1. *Selecting Products for Inclusion*

In creating a PDAB, a state must decide which drugs will be eligible for selection for the Board's analysis. States should ensure that both patented and non-patented drugs are eligible to be subject to Board review, as doing so will enable states to minimize potential patent preemption issues as identified in Part

* Treiman Professor of Law, Washington University in St. Louis School of Law.

II.A, below. However, given states' limited resources, they may choose to prioritize for affordability review certain types of products, including but not limited to those which pose affordability challenges for patients in the state, or those which are overall most costly to the entities participating in the program, including payers. This approach would resemble efforts on the federal level to focus Medicare negotiation efforts at particularly costly products.¹ Alternatively (or in addition), states may include consideration of a drug's price increases as part of the criteria for program selection—a drug whose price is increased beyond a specified amount in a particular time frame would be prioritized for affordability review. This focus would take inspiration from Medicaid, which already includes financial rebate requirements for drugs whose prices are increased at rates outpacing inflation,² and from federal proposals to extend these inflationary rebates to Medicare.³

2. Factors to Consider in Affordability and Payment Reviews

State legislatures establishing PDABs should provide criteria to help guide the Boards (and any potential outside contractors) in their performance of affordability and upper payment reviews. There are a range of potential factors to consider, including but not limited to overall system spending, patients' out-of-pocket costs, whether a drug is in shortage, and whether therapeutic alternatives are available and the price and effectiveness of those alternatives. For example, a PDAB may wish to compare a particularly costly drug to existing lower-cost therapeutic alternatives, to determine whether the costly drug provides additional clinical benefits relative to those alternatives. If it does not provide significant additional clinical benefits, the PDAB might be given the authority to set an upper payment limit for the costly drug that makes reference to the lower-cost alternative product.

More generally, in identifying factors and information that will be brought to bear in these processes, states ought to consider two additional issues that may implicate legal considerations like those articulated below. First, states may wish to consider how to solicit information—on a voluntary or a compulsory basis—from manufacturers or other industry stakeholders for the PDAB to include in its analysis. For example, the PDAB may wish to consider information about the costs incurred in developing the product in question, information that is most easily obtained from the manufacturer. States can certainly invite manufacturers to submit this type of information and provide them with the opportunity to do so, but states may also wish to compel the production of certain types of information.⁴ If states obtain this type of information, they will need to be mindful about the need to protect at least some of it from public disclosure on trade secret grounds and how doing so may be reconciled with the PDAB's broader goals of transparency in its processes. States which already have enacted transparency laws regarding drug pricing may have more experience in this area, enabling the aggregation of relevant information and empowering the PDAB to push back, where relevant, against overreaching trade secret claims.⁵

Second, states ought to consider the role external experts might play in the PDAB's activities. Many of the PDAB's activities, including the aggregation of relevant information and the performance of

¹ Elijah E. Cummings Lower Drug Costs Now Act of 2019, H.R. 3, 116th Cong, at § 101 (2019).

² 42 U.S.C. § 1396r-8(c)(2)(A). The operation of these rebates and the ways in which they might relate to an upper payment limit are discussed in more detail below in Part II.C.

³ See, e.g., Prescription Drug Pricing Reduction Act of 2019, S. 2543, 116th Cong., at § 106, 128 (2019); Elijah E. Cummings Lower Drug Costs Now Act of 2019, at § 201, 202.

⁴ Although compelling the production of this information may lead to additional litigation, existing state efforts to require drug price transparency have so far survived scrutiny on constitutional grounds. See, e.g., *Pharmaceutical Research & Manufacturers of America v. David*, No. 2:17-cv-02573-MCE-KJN, 2021 WL 22473 (E.D. Cal. Jan. 4, 2021).

⁵ See, e.g., Robin C. Feldman & Charles Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J. L. & TECH. 61 (2020).



affordability reviews, may already have been performed or may be more efficiently performed by outside experts. These experts may be based in the private sector or the public sector—for instance, if a federal drug pricing negotiation program were to be created, that program’s analyses might inform a PDAB’s reviews. Some states may wish to draw on the expertise housed within universities (public or private) to work on these issues. Providing the PDAB with the ability to incorporate or commission analyses from outside experts is likely to be useful to the Board’s operations. Organizations like NASHP may also have a role to play in providing convening structures to support state PDAB activities. It will be important, though, to ensure that final decision-making authority lies with the Board or the relevant administrative agency actor, depending on the state.

3. Potential Appellate Issues

In designing the procedures the PDAB will use in conducting its work, states may wish to consider specifying procedures for insulating certain decisions from judicial review or channeling PDAB decisions to economize on the Board’s resources. More specifically, there are a range of Board decision points that manufacturers may wish to challenge, legally, such as: the identification and selection of products for PDAB review, the procedure of conducting the affordability review and the substance of its outcome, and the procedure of establishing an upper payment limit and the substance of the limit. If manufacturers were able to challenge each and every one of these decisions at the time at which it occurs, a PDAB would find it very difficult to engage in its core activities, due to the potential need to resolve any one dispute before proceeding to the next phase of analysis.

States may seek to specify that only the setting of an upper payment limit qualifies as final action subject to review, to ensure that the Board’s resources for responding to disputes are best allocated to those Board decisions that may have an impact on pharmaceutical companies. In at least some states, this may already be the case with the backdrop of existing law. Some of the decision points prior to the setting of an upper payment limit may not themselves be subject to challenge, either because they will not qualify as final actions subject to review or because they do not in and of themselves impose an injury on a firm sufficient to confer standing. For instance, at least some states may already have a doctrinal baseline that a PDAB decision merely to select a drug for affordability review would not be ripe for challenge.

States may also consider whether they may either be required to (by a particular state administrative procedure act) or find it advantageous to construct a procedure for appeals within the PDAB structure, before pharmaceutical companies obtain judicial review. An internal appeals procedure would create space for the PDAB to review criticisms of its decisions and either to rectify any mistakes or to explain its reasons for proceeding as decided, an explanation which could then serve as part of the record on appeal to an external court.

4. Remedies for Noncompliance

Pharmaceutical manufacturers are likely to push back particularly strongly against the implementation of an upper payment limit and may take steps to make it difficult for states to operationalize this portion of their PDABs.⁶ Pharmaceutical companies or their trade organizations may make arguments that PDABs can “limit access to needed medicines” for patients, for instance.⁷ This form of argument is, in practice, a

⁶ At earlier stages, pharmaceutical firms may lobby against the inclusion of this element in any PDAB legislation or may challenge its inclusion on legal grounds, including those discussed *infra* in Part II.

⁷ See, e.g., Sean Price, *Rally at Colorado Capitol Calls for Lower Prescription Drug Prices*, COLORADO TIMES RECORDER (April 12, 2021), <https://coloradotimesrecorder.com/2021/04/rally-at-colorado-capitol-calls-for-lower-prescription-drug-prices/35707/>.

claim by companies that they would refuse to sell some or all of their products in states where a PDAB has established an upper payment limit for one or more of their products. It is important to emphasize here that pharmaceutical manufacturers are willing to sell the very same products that they sell in the United States at high prices in other countries at much lower prices—and that they make a profit at those lower prices.⁸ It is unlikely that any upper payment limit a PDAB would set would be a price at which the manufacturer could not make a profit. As a result, it may be unlikely that a company would follow through on this apparent threat not to market their products in a particular state, even though they have publicly made these arguments.⁹

States may consider including in their PDAB bills remedies for companies who withdraw their products from the state market, under these circumstances. Some of these remedies might be notice-focused, requiring manufacturers to notify states within a particular timeframe if they plan to withdraw their product or products from the state market and imposing financial penalties if they fail to do so. Others might be based off of one approach taken by Congressional Democrats, who have proposed assessing a civil penalty for firms who refuse to negotiate fairly or sell their products within a particular upper payment limit.¹⁰ States may also look to other areas of law for enforcement tools, such as states' consumer protection or unfair trade practice laws¹¹

II. Potential Legal issues for State-Based Prescription Drug Affordability Boards

Creating a PDAB may raise several legal questions, many of which are similar to those I considered in a previous NASHP brief regarding international reference pricing programs.¹² But, as with those previous proposals, states do have the ability to design their PDABs to minimize or avoid these legal barriers. This brief identifies and analyzes four main legal hurdles that states will wish to consider: patent-related preemption arguments, dormant commerce clause issues, Medicaid complications, and ERISA preemption.¹³

1. Federal Patent Preemption

If a state envisions implementing a PDAB with the authority to implement an upper payment limit of some type, they may expect that manufacturers of patented drugs will argue that federal patent law preempts

⁸ *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>.

⁹ In some cases, manufacturers have refused to sell their products in foreign countries when payers were not willing to pay as high a price as the manufacturer would accept. One example is Vertex's dispute with the UK's National Health Service over reimbursement for its new cystic fibrosis drugs. But in the large majority of cases, companies are able to reach acceptable deals with the relevant payers – as even Vertex was able to do with the NHS. 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>.

¹⁰ As one example, the bill passed by House Democrats in 2019 provides that drug manufacturers who refuse to negotiate or fail to reach an agreement on reimbursement for their product will be assessed a significant non-compliance fee. Elijah E. Cummings Lower Drug Costs Now Act of 2019, H.R. 3, § 102, 116th Cong. (2019).

¹¹ See, e.g., 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>.

¹² Rachel E. Sachs, *The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing for Prescription Drugs* (2020), <https://www.nashp.org/wp-content/uploads/2020/08/IPI-legal-analysis-8-6-2020.pdf>.

¹³ Here, my focus is on issues that are specific to the creation of a PDAB. However, there are certainly other legal issues that might arise as state legislatures consider the design of a PDAB, and attention will need to be paid with issues such as compliance with relevant state administrative law requirements, such as around when notice-and-comment rulemaking might be required.



the state’s ability to set this upper payment limit.¹⁴ In advancing this argument, manufacturers are likely to rely on *Biotechnology Industry Organization v. District of Columbia*.¹⁵ In that case, the United States Court of Appeals for the Federal Circuit was faced with determining whether patent preemption applied to a Washington, DC law that included the following provision:

It shall be unlawful for any drug manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price.¹⁶

PhRMA and BIO, the trade associations representing pharmaceutical and biotechnology firms, argued that the law was unconstitutional, particularly (though not only) on federal preemption grounds. They argued that the DC price-setting law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of”¹⁷ the federal patent law and therefore ought to be struck down under the law of conflict preemption.¹⁸ The Federal Circuit agreed, largely by reasoning that the law’s sole focus on patented drugs would “penaliz[e] high prices” and “limit[] the full exercise of the exclusionary power that derives from a patent.”¹⁹

States can choose to design their PDABs to minimize such preemption concerns. Legislative drafters should take care to ensure that PDABs can select for analysis, conduct affordability reviews of, and (if desired) impose upper payment limits on both patented and non-patented products. The author of the *BIO v. DC* opinion later explicitly distinguished his ruling regarding the DC law from a ruling on a potential future case which did not only involve patented drugs. In concurring in the denial of en banc rehearing of the case, he wrote that “[w]hether future efforts of states to regulate drug prices, which for example did not only target patent drugs or did not as significantly or directly undermine the balance of the federal patent right, would also be preempted is a question that remains for another day.”²⁰ As a result, a PDAB law that included both patented and non-patented (biosimilar and generic) products would be on stronger legal ground.

Perhaps more importantly, unlike the DC price-setting law, PDABs that include upper payment limits are not intended to regulate the price a manufacturer is able to charge for a product. PDABs are instead intended to regulate the *purchase* of the product, setting the price a payer is willing to *pay* or to provide reimbursement. In that way, PDAB laws should not directly implicate the same types of concerns present in *BIO v. DC*, where the PDAB law imposes no limits on manufacturers’ ability to charge prices, but instead alters the price a particular set of payers is willing to pay.

¹⁴ Although I consider this issue only briefly here, for a fuller analysis, 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>.

¹⁵ 496 F.3d 1362 (Fed. Cir. 2007).

¹⁶ D.C. Code § 28-4553. The statute went on to clarify that a facial instance of excessive pricing “shall be established where the wholesale price of a patented prescription drug” as sold in DC is “30% higher than the comparable price” in a set of foreign countries: the United Kingdom, Germany, Canada, or Australia. D.C. Code § 28-4554(a).

¹⁷ See *Biotechnology Industry Organization*, 496 F.3d at 1372 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)).

¹⁸ *Id.* at 1372.

¹⁹ *Id.* at 1374.

²⁰ *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 14, at 4.

2. Dormant Commerce Clause

Manufacturers would be likely to challenge an upper payment limit as set by a PDAB on dormant commerce clause (DCC) grounds.²¹ Specifically, manufacturers would likely argue that state efforts to set reimbursement rates for drugs are “designed to benefit in-state economic interests by burdening out-of-state competitors,”²² and would therefore violate the DCC, with its purpose of guarding against economic protectionism. In support of their claims, manufacturers would be able to point to a recent case, *Association for Accessible Medicines v. Frosh*,²³ in which the United States Court of Appeals for the Fourth Circuit struck down Maryland’s law prohibiting “price gouging in the sale of an essential off-patent generic drug”²⁴ on the grounds that “it directly regulates transactions that take place *outside Maryland*.”²⁵

This type of DCC claim is likely to fail for at least two reasons. First, states designing PDAB programs can choose to explicitly limit the application of their upper payment limits to sales made or products distributed in the state, limiting the DCC concerns. In *Association for Accessible Medicines*, the court specifically referenced the Maryland law’s applicability to drugs “*made available for sale*” (emphasis added) rather than drugs that were *actually sold* or distributed in Maryland as allowing Maryland to burden out-of-state transactions—to “enforce the Act against parties to a transaction that did not result in a single pill being shipped to Maryland.”²⁶ The court further distinguished other cases in which similar statutes focused specifically on in-state transactions had been upheld against DCC challenges.²⁷

Second, particularly for states located outside the Fourth Circuit, *Association for Accessible Medicines* is arguably a departure from existing DCC precedent.²⁸ The Fourth Circuit opinion itself noted that it was applying a more restrictive reading of the DCC than have some other circuits.²⁹ Courts reviewing a DCC challenge to a PDAB bill, particularly in other circuits, might well come to a different conclusion. For instance, a 2021 Sixth Circuit opinion distinguished *Association for Accessible Medicines* in upholding a Kentucky price-gouging law against a DCC challenge, noting that unlike Maryland’s law, which “expressly targeted upstream sales that took place wholly outside of Maryland,” “Kentucky’s price-gouging statutes apply to transactions involving Kentucky consumers and only indirectly impact out-of-state transactions.”³⁰ More generally, the legal analysis in the *Association for Accessible Medicines* opinion has been criticized, particularly by health law scholars, as departing from the central purpose of the DCC. That is, the Maryland law was not motivated by economic protectionism in the way that other laws which have run afoul of the DCC in the past have been—it does not aim to disadvantage drug manufacturers in other states to favor sales in Maryland.³¹

²¹ 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.

²² *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)).

²³ 887 F.3d 664 (4th Cir. 2018).

²⁴ *Id.* at 666; *see also* Md. Code Ann. § 2-802(a).

²⁵ *Ass’n for Accessible Medicines*, 887 F.3d at 674.

²⁶ *Id.* at 671.

²⁷ *Id.* at 670–71.

²⁸ Even the opinion in *Association for Accessible Medicines* itself was made over a strong dissent, arguing that the statute required an in-state sale for its applicability. *Id.* at 678–79 (Wynn, J., dissenting).

²⁹ *Id.* at 670.

³⁰ *Online Merchants Guild v. Cameron*, 995, F.3d 540, 558 n.7 (6th Cir. 2021).

³¹ *See, e.g.,* Christopher Robertson, *Will Courts Allow States to Regulate Drug Prices?*, 379 NEW ENGLAND J. MED. 1000, 1001 (2018); *see also* *Ass’n for Accessible Medicines*, 887 F.3d at 675 (Wynn, J., dissenting) (arguing that “the Maryland statute –

However, manufacturers would still be likely to challenge a statute that applied only to in-state transactions, relying on a different strain of DCC doctrine, which focuses not on economic protectionism but simply on state regulation of extraterritorial conduct.³² They would argue that state efforts to regulate prices paid for in-state transactions would necessarily impact sales that occur “upstream from consumer retail sale” that will “occur almost exclusively outside the state.”³³ Because of the complexity of the prescription drug supply chain, it is not necessarily the case that a pharmaceutical manufacturer would sell directly to an in-state payer or pharmacy, and instead that transaction is likely to be mediated by a number of third-party intermediaries, located both in- and out-of-state relative to any particular patient who ultimately receives the medication, and pricing negotiations with the manufacturer or a wholesaler might occur both in- and out-of-state as well. Manufacturers may therefore argue that regulating the terms of sale to an in-state patient or payer could impact the terms of these out-of-state negotiations and transactions.³⁴

It is unlikely that this argument would succeed in invalidating a PDAB that included an upper payment limit. Then-Judge (now Justice) Gorsuch has referred to the extraterritoriality line of DCC doctrine as “the most dormant” of all the DCC doctrines, noting that the Supreme Court has used the “extraterritoriality principle to strike down state laws only three times,”³⁵ all in cases in which the Court faced “(1) a price control or price affirmation regulation, (2) linking in-state prices to those charged elsewhere, with (3) the effect of raising costs for out-of-state consumers or rival businesses”³⁶—conditions that do not apply to proposed PDAB legislation. Given the similarity of the PDAB’s approach to Maine’s efforts to obtain lower drug prices in its Medicaid program, an effort the Supreme Court upheld against an extraterritoriality-based DCC challenge in 2003,³⁷ these arguments are similarly likely to fail here.

More generally, given that both Justice Gorsuch and Justice Thomas have questioned the validity of the DCC more broadly on the grounds that it is atextual, it is not clear that the current Supreme Court would uphold most challenges to state laws on this basis.³⁸ The Supreme Court may soon answer this question more clearly, as it has recently granted certiorari on a case (to be heard during the Court’s Term beginning in October 2022) which poses the following question: “[w]hether allegations that a state law has dramatic economic effects largely outside of the state and requires pervasive changes to an integrated nationwide industry state a violation of the dormant Commerce Clause, or whether the extraterritoriality principle described in this Court’s decisions is now a dead letter.”³⁹

which applies equally to in-state and out-of-state manufacturers and distributors – does not implicate the concerns that lie at the heart of the Supreme Court’s dormant Commerce Clause jurisprudence: economic protectionism,” among other factors).

³² *Ass’n for Accessible Medicines*, 887 F.3d at 669.

³³ *Id.* at 671.

³⁴ The Fourth Circuit’s opinion in *Association for Accessible Medicines* adopted this version of the doctrine, in concluding that even if the Maryland law applied only to drugs ultimately sold in Maryland, the law had the effect of regulating upstream extraterritorial transactions, which was impermissible under the DCC. *Id.* at 671.

³⁵ *Energy & Env’t Legal Inst. v. Epel*, 793 F.3d 1169, 1172 (10th Cir. 2015) (Gorsuch, J.). It is not even clear that all of those cases were entirely driven by the extraterritoriality prong of the doctrine. *See, e.g., American Beverage Ass’n v. Snyder*, 735 F.3d 362, 381 (6th Cir. 2013) (Sutton, J., concurring) (noting that in those cases, the extraterritoriality doctrine was not “indispensable,” concluding that “I am not aware of a single Supreme Court dormant Commerce Clause holding that relied exclusively on the extraterritoriality doctrine to invalidate a state law”).

³⁶ *Energy & Env’t Legal Inst.*, 793 F.3d. at 1173.

³⁷ *Pharmaceutical Research & Manufacturers of America v. Walsh*, 538 U.S. 644, 669 (2003)

³⁸ *See South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2100 (2018) (Gorsuch, J., concurring); *Comptroller of Treasury of Md. v. Wynne*, 575 U.S. 542, 578 (2015) (Thomas, J., dissenting).

³⁹ *See SCOTUSblog, National Pork Producers Council v. Ross* (2022), <https://www.scotusblog.com/case-files/cases/national-pork-producers-council-v-ross/>.

3. Medicaid

States may face two additional legal complications relating to Medicaid, involving 1) the role of an upper payment limit and 2) the role of the Medicaid best-price requirement. The first complication, regarding the role of an upper payment limit, may have different implications depending on states' choices about whether and how to include Medicaid in designing their PDABs. States seeking to implement affordability reviews and to recommend but not require the use of an upper payment limit in state Medicaid programs would find it relatively easy to do so. The state might be able to do so under an existing State Plan Amendment permitting the state to obtain supplemental rebates in Medicaid, or if a new Amendment is required, it would likely be granted easily, as have other innovative payment models states have used in the supplemental rebate context.⁴⁰

But a state might find it more difficult to impose a required upper payment limit in its Medicaid program in the event that the upper payment limit in a particular case was lower than the already-existing mandatory statutory rebates that manufacturers must pay for access to the program. The state might need to submit an 1115 waiver request, asking the Centers for Medicare and Medicaid Services (CMS) for permission to waive elements of the existing coverage and reimbursement requirements. During the Trump Administration, CMS took conflicting positions as to whether such waivers were legally permissible. In 2018, CMS declined to approve an 1115 waiver from Massachusetts that requested waivers of certain coverage and reimbursement rules.⁴¹ In doing so, CMS did not explain its legal reasoning. Later, in early 2021, CMS approved a request from Tennessee to waive these requirements, in the context of a larger block grant program.⁴² Most recently, Oregon has asked CMS to approve a narrow waiver focused on particular types of medications,⁴³ and the Biden Administration's ruling on that waiver will be instructive for states in this context as well.⁴⁴

A second potential complication relates to Medicaid's best-price requirement. As noted above, pharmaceutical manufacturers wishing to sell products to Medicaid programs must provide Medicaid with significant statutory discounts off of the average manufacturer price of the drug—but if the manufacturer offers even larger discounts to a set of other payers, Medicaid is entitled to that “best price” provided to

⁴⁰ 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-medicaid-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>.

⁴¹ Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 NEW ENG. J. MED. 1002, 1002 (2018).

⁴² Cathy Kelly, *Tennessee Medicaid Gets US Approval for Closed Formulary as Part of “Capped” Spending Program*, PINK SHEET (Jan. 8, 2021), <https://pink.pharmaintelligence.informa.com/PS143575/Tennessee-Medicaid-Gets-US-Approval-For-Closed-Formulary-As-Part-Of-Capped-Spending-Program>.

⁴³ Ed Silverman, *Oregon Withdraws a Waiver Request to Run a Closed Medicaid Formulary*, STAT (Feb. 28, 2022), <https://www.statnews.com/pharmalot/2022/02/28/oregon-medicaid-cms-alzheimer-biogen/> (noting that “state officials are still seeking to exclude certain drugs from Medicaid when effectiveness evidence is lacking”).

⁴⁴ During the Trump Administration, CMS had claimed that it would only consider granting these waivers within the context of a block grant program like that later granted to Tennessee. Sarah Oweremohle & Sarah Karlin-Smith, *Drugmakers Blast Medicaid Block Grants*, POLITICO (Jan. 31, 2020), <https://www.politico.com/newsletters/prescription-pulse/2020/01/31/drugmakers-blast-medicaid-block-grants-784910>. However, the legal basis for this statement was unclear.

another payer.⁴⁵ It is possible, though perhaps unlikely depending on the products at issue and the considerations used by the PDABs in conducting affordability reviews, that an upper payment limit might be set in a way that triggered the manufacturer's Medicaid best price obligations.⁴⁶ That would mean that a manufacturer agreeing to sell to private payers in one state at its PDAB's upper payment limit might need to offer that price to state Medicaid programs nationwide.⁴⁷ The financial ramifications for a manufacturer whose product had high Medicaid market share might be significant, such that it would be more important for states to have considered potential remedies for noncompliance, as noted above in Part I.

4. ERISA Preemption

To the extent that a PDAB possesses the authority to establish an upper payment limit, states ought to consider carefully the scope of insurers to which the PDAB's determinations applies. States themselves serve as payers (particularly in their capacity as employers), and certainly may choose to apply upper payment limits to the state's own insurance programs for its employees. More generally, states must navigate carefully around potential preemption concerns regarding the Employee Retirement Income Security Act of 1974 (ERISA). ERISA significantly restricts states' ability to directly regulate private health insurance, especially in the context of self-funded insurance plans.⁴⁸ As such, it would be difficult for a state to require an ERISA plan to adopt an upper payment limit included in the PDAB system. Because of the large portion of privately insured patients who receive their insurance through ERISA plans, this is a potentially concerning limitation on the scope of a potential PDAB. Unlike patent preemption or the DCC objections, ERISA preemption would not likely prevent states from creating a PDAB at all, but could potentially limit the ability to create a PDAB that would benefit a states' citizens broadly.

States have at least two options for limiting their exposure to ERISA preemption issues. First, states may extend the PDAB's benefits, including its upper payment limits, to private ERISA plans on an opt-in basis. Because one of the goals of the law is to enable payers to obtain better prices than they might otherwise be able to access, it might be expected that plans would choose to opt-in to lower costs for both them and their beneficiaries. States might also consider including a clear severability clause, ensuring that the invalidation of any one provision of the law would not impact the remainder of the program.

Second, recent Supreme Court precedent on ERISA would support state efforts to regulate pharmacy benefit managers (PBMs) directly, rather than insurers. In *Rutledge v. Pharmaceutical Care Management Association*,⁴⁹ the Supreme Court unanimously held that Arkansas' statute regulating PBMs used by health plans (though not the health plans themselves) and their payment practices was not preempted

⁴⁵ 42 U.S.C. § 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).

⁴⁶ In some cases, it may be possible for a state to avoid triggering traditional best price obligations if a manufacturer were to engage in certain types of innovative contracting models. Edwin Park, *CMS Issues New Guidance on Variable Best Price Reporting Under the Medicaid Drug Rebate Program* (March 25, 2022), <https://ccf.georgetown.edu/2022/03/25/cms-issues-new-guidance-on-variable-best-price-reporting-under-the-medicaid-drug-rebate-program/>. But these are unlikely to apply to the PDAB and upper payment limit context.

⁴⁷ Importantly, this would not apply to a state's implementation of a PDAB upper payment limit in its Medicaid program (rather than for private payers). A state could implement that limit through a supplemental rebate agreement, enabling the state to avoid triggering best-price obligations in other states' Medicaid programs. 42 C.F.R. § 447.505(c)(7) (2016).

⁴⁸ Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PENN. L. REV. 389, 420–21 (2020).

⁴⁹ 141 S. Ct. 474 (2020).



by ERISA.⁵⁰ One key reason for this holding was that “the Act does not directly regulate health benefit plans at all, ERISA or otherwise”—rather, “it applies to PBMs whether or not they manage an ERISA plan.”⁵¹ States may therefore be on strong legal ground if they seek to implement PDABs through regulations on PBMs that are administrative contractors of ERISA plans.⁵²

III. Conclusion

States may choose to pursue PDAB legislation as one of many strategies to lower the prices payers and patients pay for prescription drugs. Although there are difficult design choices and legal issues that may arise as part of their design, these issues can be addressed through careful drafting and implementation. While some uncertainty surely remains regarding the outcome of potential legal challenges, states can take steps to design the PDAB in light of existing precedent and doctrine to mitigate these concerns.

* Rachel E. Sachs, JD, MPH is associate professor at Washington University in St. Louis School of Law.

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⁵⁰ *Id.* at 478.

⁵¹ *Id.* at 481.

⁵² See Erin C. Fuse Brown & Elizabeth Y. McCuskey, *The Implications of Rutledge v. PCMA for State Health Care Cost Regulation*, HEALTH AFFAIRS FOREFRONT (Dec. 17, 2020), <https://www.healthaffairs.org/doi/10.1377/forefront.20201216.909942/full/>.