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NASHP's Proposal for State-Based Prescription Drug Affordability Boards[1]

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Several states have recently passed legislation creating 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, conducting 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 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 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 amounts 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 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 because they shape the potential legal challenges (identified in Part II) which may be brought.

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A. 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 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 legislation on the federal level to focus Medicare negotiation efforts on drugs with particularly high expenditures under the Medicare program.[2] 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 and Medicare, which already include financial rebate requirements for drugs whose prices are increased at rates outpacing inflation.[3]

B. 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 relevant entities 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.[4] States can certainly invite manufacturers to submit this type of information and provide them with the

[2] 42 U.S.C. § 1320f-1(b)(1).

[3] 42 U.S.C. § 1396r-8(c)(2)(A); 42 U.S.C. § 1395w-114b. 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.

[4] The Medicare drug price negotiation program as created by the Inflation Reduction Act requires Medicare to consider the "research and development costs of the manufacturer for the drug" as one factor for use in the negotiation process, alongside other factors, including current unit costs of production and distribution, prior federal financial support, and other factors. The statute specifically identifies the data underlying these factors as being "submitted by the manufacturer." 42 U.S.C. § 1320f-3(e)(1).

opportunity to do so, but states may also wish to compel the production of certain types of information.[5] 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 that 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.[6]

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 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, states conducting affordability reviews of drugs that have already been selected for the Medicare drug price negotiation program might consider whether Medicare itself will publish information that may be useful to PDAB efforts or whether members of the public have generated information to support the federal program that might be useful to state PDABs. 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 such as 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.

C. 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.

[5] Although compelling the production of this information may lead to additional litigation, at least some 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). Challenges in other jurisdictions, however, have yielded different results at this stage of litigation. *See, e.g.*, Pharmaceutical Research & Manufacturers of America v. Stolfi, No. 6:19-cv-01996-MO (D. Or. Mar. 19, 2024).

[6] *See, e.g.*, Robin C. Feldman & Charles Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 Yale J. L. & Tech. 61 (2020).

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 to rectify any mistakes or to explain its reasons for proceeding as decided, an explanation that could then serve as part of the record on appeal to an external court.

D. 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.[7] Pharmaceutical companies or their trade organizations may make arguments that PDABs can "limit access to needed medicines" for patients, for instance.[8] This form of argument is, in practice, a 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 U.S. at high prices in other countries at much lower prices — and that they make a profit at those lower prices.[9] 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.[10]

[7] 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.

[8] *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/.

[9] *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.

[10] 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 U.K.'s National Health Service (NHS) 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*

States may consider including in their PDAB bills remedies against companies that 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. States may also look to other areas of law for enforcement tools, such as states' consumer protection or unfair trade practice laws.[11]

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 Employee Retirement Income Security Act of 1974 (ERISA) preemption.[13]

A. 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 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, D.C., 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]

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.

[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.

[14] Although I consider this issue only briefly here, for a fuller analysis, see Robin Feldman et al., S*tates' 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 D.C. 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).

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 D.C. law from a ruling on a potential future case that 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 D.C. 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 amount 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 amount a particular set of payers is willing to pay.

[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.

B. Dormant Commerce Clause

Manufacturers would be likely[21] to challenge an upper payment limit as set by a PDAB on dormant commerce clause (DCC) grounds.[22] Manufacturers might argue that state efforts to set reimbursement rates for drugs would violate the DCC in multiple ways. They might argue, for example, that such efforts are "designed to benefit in-state economic interests by burdening out-of-state competitors"[23] or that they have the "practical effect of controlling commerce outside the state."[24] In support of their claims, manufacturers might point to a 2018 case, *Association for Accessible Medicines v. Frosh*,[25] 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"[26] on the grounds that "it directly regulates transactions that take place *outside Maryland.*"[27]

As an initial matter, 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 any 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."[28] The court further distinguished other cases in which similar statutes focused specifically on in-state transactions had been upheld against DCC challenges.[29]

Other courts might also distinguish *Association for Accessible Medicines* if faced with a PDAB program employing different statutory language.[30] 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."[31] Even on its own terms, particularly for states located outside the Fourth Circuit, *Association for Accessible Medicines* is

[21] This has already occurred, though a court has not yet ruled on the topic. *See* Amgen v. Mizner, Motion for Summary Judgment, No. 1:24-cv-00810-NYW-SBP (D. Col. June 24, 2024).
[22] 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.
[23] 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)).
[24] Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 371 (2023).
[25] 887 F.3d 664 (4th Cir. 2018).
[26] *Id.* at 666; *see also* Md. Code Ann. § 2-802(a).
[27] *Ass'n for Accessible Medicines*, 887 F.3d at 674.
[28] *Id.* at 671.
[29] *Id.* at 670–71.
[30] *Association for Accessible Medicines* might also be distinguished as a case that predates the 2023 Supreme Court decision in *National Pork Producers*, explored *infra.*
[31] Online Merchants Guild v. Cameron, 995, F.3d 540, 558 n.7 (6th Cir. 2021).

arguably a departure from existing DCC precedent,[32] as the Fourth Circuit opinion itself noted that it was applying a more restrictive reading of the DCC than have some other circuits.[33]

To be sure, manufacturers would still be likely to challenge a statute that applied only to in-state transactions, relying on the strain of DCC doctrine focusing not on economic protectionism but simply on state regulation of extraterritorial conduct.[34] 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."[35] 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.[36]

A 2023 Supreme Court decision recognizing limits on the scope of the DCC, *National Pork Producers Council v. Ross*,[37] is likely to make it difficult for manufacturers to prevail on such challenges. As expert commenters have concluded, the Court "rul[ed] unanimously that extraterritoriality was not a standalone DCC test."[38] Writing for five justices, Justice Gorsuch wrote that the "antidiscrimination principle [of economic protectionism] lies at the 'very core' of our dormant Commerce Clause jurisprudence,"[39] recasting cases that the petitioners argued established an "almost per se" extraterritoriality principle as cases that "typif[y] the familiar concern with preventing purposeful discrimination against out-of-state economic interests."[40] Gorsuch even specifically recognized the "strange places" the creation of such a "per se" rule against state laws with extraterritorial effects could lead, noting that "[i]n our interconnected national marketplace, many (maybe most) state laws have the 'practical effect of controlling' extraterritorial behavior."[41] Writing for four justices, Chief Justice Roberts' concurrence in part and dissent in part "agree[d] with the Court's conclusion that our precedent does not support a per se rule against state laws with 'extraterritorial' effects."[42]

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[32] 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).
[33] *Id.* at 670.
[34] *Ass'n for Accessible Medicines*, 887 F.3d at 669.
[35] *Id.* at 671.
[36] 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.
[37] 598 U.S. 356 (2023).
[38] Jack Goldsmith, Alan Sykes, *The California Effect, Process-Based Regulation, and the Future of Pike Balancing*, 2023 Sup. Ct. Rev. 125, 128 (2023).
[39] *Ross*, 598 U.S. at 369.
[40] *Id.* at 371.
[41] *Id.* at 374.
[42] *Id.* at 394 (Roberts, C.J., concurring in part and dissenting in part).

Applying this reasoning, state efforts to establish PDABs or construct upper payment limits should be on relatively strong ground. States have not been motivated to establish PDABs in order to advantage in-state companies relative to out-of-state competitors or otherwise to engage in economic protectionism goals, but are instead motivated to address the problem of high prescription drug prices for the state's residents and insurers. Nothing about a PDAB depends on whether a pharmaceutical company is an in- or out-of-state entity, to put it differently. As such, even if some PDABs may be structured in a way as to impact upstream out-of-state transactions where the ultimate dispensation takes place within the relevant state (other PDABs may not be structured in such a way), that extraterritorial effect is not evidence of economic protectionism or discrimination against out-of-state entities.

At the same time, the court in *Ross* appears to have left open the possibility for plaintiffs to assert so-called "*Pike* balancing"[43] challenges, in which a state law may be invalidated on DCC grounds upon a showing that "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits."[44] A majority of five justices signed on to Gorsuch's analysis describing *Pike* itself as part of the court's antidiscrimination case law, noting that "the *Pike* line serves as an important reminder that a law's practical effects may also disclose the presence of a discriminatory purpose."[45] If the purpose of *Pike* balancing is to reveal state laws that may involve intentional discrimination "as illuminated by those laws' practical effects,"[46] as noted above, because any out-of-state impacts of PDABs are not driven by discriminatory motives, it is not likely that *Pike* balancing would be appropriate to apply in such a case.

However, subsequent portions of the majority's analysis are splintered, and the justices in the majority disagree as to *how* courts ought to assess claims of *Pike* balancing. Four justices concluded that plaintiffs "must plead facts 'plausibly,' suggesting a substantial harm to interstate commerce; facts that render that outcome a 'speculative' possibility are not enough."[47] This pleading standard is articulated as a rigorous one — plausible allegations that "*some* out-of-state firms may face difficulty complying" may be insufficient where "*other* out-of-state competitors … may choose to modify their existing operations or create new ones to fill the void."[48] Under this theory, it is possible but difficult for plaintiffs to make such a case. Three justices would have gone further, essentially concluding that "no court is equipped to undertake" the type of balancing urged by the petitioners here or in related DCC cases, particularly in cases where "competing goods are incommensurable."[49]

[43] So named for *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970).
[44] *Id.* at 142.
[45] *Ross*, 598 U.S. at 377.
[46] *Id.* at 389 n. 4.
[47] *Id.* at 385.
[48] *Id.*
[49] *Id.* at 382.

Despite these disagreements, five justices agreed that the arguments advanced in *Ross* would result in the Court "prevent[ing] a State from regulating the sale of an ordinary consumer good within its own borders on nondiscriminatory terms — even though the *Pike* line of cases they invoke has never before yielded such a result."[50] Because PDABs do not and are not intended to discriminate against interstate commerce (particularly when compared with intrastate commerce), a court confronting a DCC challenge post-*Ross* should recognize the far more limited state of the doctrine. Many circuit courts that have considered DCC challenges after *Ross* have similarly centered the role of nondiscrimination against interstate commerce in evaluating such challenges, on the grounds that "the dormant Commerce Clause does not prohibit laws solely because they have extraterritorial reach absent protectionist intent or effect."[51]

C. Medicaid

States may face two additional legal complications relating to Medicaid, involving the role of an upper payment limit and 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 their state Medicaid program 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.[52]

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. In recent years, CMS has taken 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.[53] In doing so, CMS did not explain its legal reasoning. In early

[50] *Id.* at 391.

[51] New Jersey Staffing All. v. Fais, No. 23-2419, 2024 WL 3515883, at *4 (3d Cir. July 24, 2024); *see also* Forever Fencing, Inc. v. Bd. of Cnty. Commissioners of Leavenworth Cnty., No. 23-3140, 2024 WL 3084973, at *2 (10th Cir. June 21, 2024); Rest. L. Ctr. v. City of New York, 90 F.4th 101, 118-19 (2d Cir. 2024).

[52] *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.

[53] Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 New Eng. J. Med. 1002, 1002 (2018).

2021, CMS approved a request from Tennessee to waive these requirements, in the context of a larger block grant program.[54] More recently, Oregon asked CMS to approve a narrow waiver focused on particular types of medications and subsequently withdrew its request.[55]

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 another payer.[56] 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.[57] 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.[58] 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.

D. 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.[59] 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

[54] 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.

[55] 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/.

[56] 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).

[57] 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.

[58] 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).

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

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 it 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 the plans 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*,[60] 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 by ERISA.[61] 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."[62] 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.[63]

III. Conclusion

States may choose to pursue PDAB legislation as one of many strategies to lower the amounts 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.

[60] 141 S. Ct. 474 (2020).
[61] *Id.* at 478.
[62] *Id.* at 481.
[63] 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/do/10.1377/forefront.20201216.909942/full/.