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MEMORANDUM

CLIENT-MATTER NUMBER
999400-6276

TO: Alyssa R. Vangeli
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Relations, Health Care for All

FROM: Foley & Lardner LLP

DATE: May 29, 2019

RE: Analysis of Proposed Massachusetts Drug Pricing Legislation

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I. INTRODUCTION

Health Care for All ("HCFA") has asked for our view as to whether the upper payment limit ("UPL") provision in HCFA's proposed Omnibus Prescription Drug Bill (otherwise known as An Act For Affordable Prescription Drugs For Massachusetts (the "Act")) would likely survive a challenge based on ERISA preemption or the Dormant Commerce clause of the United States Constitution. The specific UPL provision is found in the Act's proposed new Section 10A to Chapter 6D of the Massachusetts General Laws. As currently drafted, and as we have discussed, we believe that issues which create the potential of an adverse ruling exist. As a result, we have suggested a number of changes designed to preserve the overall goals of the legislation, but limiting its potential reach with respect to limits on transactions which occur out of the Commonwealth. Our suggested revisions to that statutory language is attached to this memo. The following analysis assumes adoption of our suggested revisions.

A. Overview of the Act

Chapter 12C, as amended by the Act, would provide the Massachusetts Center for Health Information Analysis ("CHIA") significant new authority to require drug manufacturers, pharmacy benefit managers ("PBMs"), and others to report information to CHIA to allow it to study the impact of drug manufacturer pricing factors and methods as well as PBM business models for drug costs. One purpose of these new reporting obligations is to allow CHIA to identify "unreasonable or excessive" drug costs as defined by quantitative thresholds for drug costs or drug cost increases, or cost increases that could lead to increasing health care expenditures over CHIA's heath care cost growth benchmark, or otherwise create significant challenges to the affordability of health care in the Commonwealth, and to report such findings to the Massachusetts Health Policy Commission ("Commission").

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New Section 10A of Chapter 6D would authorize the Commission to set a UPL for drugs purchased in the Commonwealth at a price which the Commission deems to be excessive based on information provided by CHIA. The UPL would apply to all purchases of the drug in the Commonwealth, whether they are wholesale or retail purchases, including purchases by uninsured consumers and consumers with prescription drug benefit coverage having a copayment or other financial responsibility for some portion of the cost of the drug, as well as purchases reimbursed by payers (whether private or governmental, including in the payer's capacity as an administrative service organization, third party administrator, contractor or agent for a third party) that are responsible for reimbursing or indemnifying the purchasers for some or all of the cost of the drug. We have assumed that such payers would be limited to those falling within the definitions of the terms "public health care payers" and "private health care payers" as defined in General Laws Ch. 6D, § 1, as may be amended by the proposed legislation with our suggested revisions.[1]

B. Our Conclusions

In our discussions with you, we have highlighted the limitations that federal Courts have placed on state statutes that impose regulatory burdens on ERISA plans and/or transactions in interstate commerce. Based on our suggested revisions to the proposed legislation, we believe that the portions of the Act upon which we have been asked to comment would, more probably than not, withstand judicial challenges based on claims of either ERISA preemption or interference with the Dormant Commerce Clause.

II. ANALYSIS

A. ERISA Preemption

While the plethora of dueling Supreme Court and lower court cases addressing the scope of ERISA preemption complicates any preemption legal analysis[2], we believe that there are strong arguments that the UPL provision, as a law of general application that regulates an area of the law that falls within the traditional authority of the state, should withstand a challenge on ERISA preemption grounds. That said, there are certain parts of the Act as currently drafted that do raise potential ERISA preemption concerns. To address these concerns, we suggest that self-funded plans be excluded from the UPL provisions of the Act, unless the plan voluntarily and affirmatively "opts-in" to the UPL provisions of the Act by giving prior written notice to the Commission.[3] We

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[1] This would exclude self-funded plans unless the self-funded plan affirmatively elects to be covered by the ACT's UPL provisions; and would include private payers in their capacity as an administrative service organization, third party administrator, contractor or agent for any third party.

[2] The Supreme Court alone has expressed its views on the scope of ERISA preemption more than times.

[3] To further support the ERISA preemption analysis we suggest that the opt-in provision apply to all self-funded plans, not just those subject to ERISA.

have suggested this revision because federal courts have found that optional state regulatory schemes that can be opted-into by self-funded plans, as opposed to mandatory restrictions or mandates, do not give rise to ERISA preemption. Given that there is a benefit to this election, we believe that many such plans will seek to take advantage of the UPL provisions.

1. Types of ERISA Preemption

Section 514 of the Employee Retirement Income Security Act of 1974, as amended ("ERISA") provides that ERISA supersedes "any and all State laws as they …relate to any employee benefit plan" covered by the statute. 29 U.S.C. § 1144(a). Section 514 contains an exception from preemption for certain types of state laws, including those regulating insurance (the "savings clause"), and an exception to the exception (the "deemer clause") that precludes a state from regulating an ERISA plan as an insurance company.

When first addressing the scope of preemption under Section 514, the Supreme Court stated that a "law 'related to' an employee benefit plan in the normal sense of the phrase, if it has a *connection with or reference to such a plan*," and that "Congress used the words 'relate to'… "in their broad sense" and intended not to preempt "only laws specifically designed to affect employee benefit plans." *Shaw v. Delta Air Lines, Inc.,* 463 U.S. 85, 96-97 (1983) (emphasis added). However, even in its earliest cases, the Court recognized that the scope of ERISA preemption was subject to limits, finding that "some state actions may affect employee benefit plans in too tenuous, remote or peripheral a manner to warrant that the law 'relates' to the plan." *Shaw* at 100, n. 21.

Based on *Shaw*, the courts have tended to analyze whether a state law has an impermissible "connection with" ERISA plans or, alternatively, impermissibly makes "reference to" such a plan.

2. "Connection With" Preemption

Over time, the Supreme Court has recognized two specific analytic elements that needed to be considered in determining whether a state law has an impermissible "connection with" ERISA. First, general federal preemption analysis starts from the presumption that Congress does not intend to supplant state law, particularly when the state law falls under the historic police powers of the state, unless Congress' intent was clear and manifest in the legislation. *New York State Conference of Blue Cross Blue Shield Plans v. Travelers Insurance Company,* 514 U.S. 645, 654-655. Second, because the ERISA text is not particularly helpful in determining when a state law should be preempted and application of the "connection with" analysis under *Shaw* should focus on Congress' intent in including Section 514 in the statute. As the Court in *Travelers* notes "[i]f 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes preemption would never run its course" for relations stop nowhere. *Travelers* at 655.

Travelers involved an ERISA preemption challenge to a New York law that imposed a surcharge of up to 24% on all hospital bills, other than bills of patients covered by a Blue

Cross/Blue Shield plan, HMO or Medicaid.[4] In other words, the law did not directly regulate ERISA plans. Rather, it regulated what the hospital charged its patient, which differed based on whether the patient was covered by a Blue Cross Blue Shield plan or another plan. Under *Shaw*, the issue before the Court was whether the indirect impact of the surcharges on ERISA plans was "too remote, tenuous or peripheral" to relate to such plans.

Following *Shaw* and its progeny, the District Court found that even a law of general application that was not specifically designed to affect employee benefit plans and that had only an indirect effect on such plans "may nevertheless be considered to 'relate to' [ERISA] plan[s] for preemption purposes." *The Travelers Insurance Company v. Cuomo,* 813 F. Supp. 996, 1002 (S.D. N.Y. 1993) (quoting *Smith v. Dunham-Bush, Inc.*, 959 F.2d 6, 9 (2d Cir. 1992). Specifically, the court found the New York law was preempted because the indirect economic impact it had on ERISA plans was substantial enough to warrant preemption. In the court's view, because the surcharges imposed a significant financial burden on commercial insurers and HMOs that provide services to employee benefit plans that would likely be passed through to such plans, the surcharges could impact the structure or administration of such plans in the form of increased participant costs or reduced benefits, as well as "impos[ing] 'requirements' on use of plan resources" that demonstrated an impermissible connection to ERISA plans." 813 F. Supp. at 1004.

On appeal, the Second Circuit, after describing Section 514 "as a veritable Sargasso Sea of Obfuscation", confirmed the holding of the District Court that the surcharges, by increasing the costs to commercial insurers and HMOs that would be passed on to their plan clients, interfered with the choices that benefit plans have for health coverage and, thus, impermissibly interfered with plan structure and administration. *The Travelers Insurance Company v. Cuomo* 14 F. 3d 708 (2d. Cir. 1993).

The Supreme Court reversed the Second Circuit finding that the surcharges did not have an impermissible connection with ERISA plans. In doing so, the Court first focused on whether Congress clearly intended to preempt a state's ability to regulate the cost of care.

> "But this still leaves us to question whether the surcharge laws have a 'connection with' the ERISA plans, and here an uncritical literalism is no more help than trying to construe 'relate to'. For the same reasons that infinite relations cannot be the measure of pre-emption, neither can infinite connections. We simply must go beyond the unhelpful text and the frustrating difficulty of defining its key term, and look instead to the objectives of the ERISA statute as a guide to the scope of the state law that Congress understood would survive." 514 U.S. at 655-656.

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[4] HMOs were subject to a separate surcharge levied directly on the HMOs.

The Court found that Congress did not intend to regulate a state's ability to regulate the cost of care.

> "While Congress's extension of pre-emption to all 'state laws relating to benefit plans' was meant to sweep more broadly than 'state laws dealing with the subject matters covered by ERISA [,] reporting, disclosure, fiduciary responsibility, and the like,' nothing in the language in the Act or the context of its passage indicates that Congress chose to displace general health care regulation, which historically has been a matter of local concern." 514 U.S. at 661 (citations omitted).

Rather the Court held that indirect economic effect does not trigger ERISA preemption, unless it produces "such acute, albeit indirect, economic effect … as to force an ERISA plan to adopt a specific scheme of substantive coverage or effectively restrict its choice of insurers, which the New York did not do. *Travelers* at 668.[5][6]

The proposed UPL provision, like the law at issue in *Travelers*, is a law of general application that (i) is intended to regulate the cost of care (a matter of local concern), (ii) is not specifically directed at employee benefit plans, and (iii) has only an indirect, and then positive, financial impact on such plans. It differs only in that it is intended to control prices paid by purchasers of drugs, rather than impose a surcharge on such care.

Accordingly, the analysis in *Travelers* as to why the surcharges did not have an impermissible connection with ERISA plans should apply equally to the UPL provision which also should not produce "such acute, albeit indirect, economic effect … as to force an ERISA plan to adopt a specific scheme of substantive coverage or effectively restrict its choice of insurers."[7] Therefore, we believe that the proposed UPL provisions, with one exception noted below, should not be subject to "connection with" preemption under ERISA.

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[5] Both the District Court and Court of Appeals in *Travelers* focused solely on the impact of the surcharges on commercial insurance companies and HMOs, and not self-insured funds that also were expressly covered by the New York law. As a result, the Court left the impact of the surcharge on self-insured funds for consideration by the Court of Appeals on remand. On remand, the 2d. Circuit found no basis for not applying the Court's analysis as applied to commercial insurers and HMOs to self-insured funds and held that the surcharges were also preempted when applied with respect to self-insured funds.

[6] The Court's analysis conformed to the position taken by the DOL in its filing as *amicus* with the 2d. Cir .that ERISA preemption generally should not apply to laws of general application that have only indirect impact on ERISA plans.

[7] While the UPL provision would not impact benefit structures or other protected areas under ERISA, as discussed below, certain other aspects of the proposed legislation do give rise to potential ERISA preemption issues.

3. <u>"Reference To" Preemption</u>

Under *Shaw*, a state law may also be preempted to the extent the law includes an impermissible reference to an ERISA plan. However, like the "connection with" standard, the Court's view as to when a reference to ERISA is impermissible has changed over time from a very literal application of the language of the statute to a more nuance approach focusing on the purpose of the statutory provision itself.

As noted, while earlier cases applied the reference test quite literally, in *Travelers* the Court found that the "reference to" analysis could be "ruled out", even though the state law referred to "self-insured funds" which earlier courts would have found to be impermissible. Preemption did not pertain because the surcharges were imposed on patients "regardless of whether commercial coverage or membership, respectively is ultimately secured by an ERISA plan, private purchase or otherwise, with the consequence that the surcharge statutes cannot be said to make 'reference to' ERISA plans in any manner." *Travelers* at 656.

The "reference" to analysis in *Travelers* would appear equally applicable to the UPL provision in that the legislation does not regulate employee benefit plans, but rather regulates the amount that a purchaser of a drug has to pay (i.e., can be charged) for the drug, This is similar to the surcharges in *Travelers* that only impacted what the hospital could charge a patient for its services, regardless of whether the patient was or was not insured or covered by an employee benefit plan.

Despite the fact that the Court in *Travelers* effectively held that a statute that referred to patients of "self-insured funds", which would encompass self-insured ERISA plans, did not make an impermissible reference to such plans, we must express the caution that the 8th Circuit Court of Appeals has recently held, in two separate cases, that a direct or even implied reference to ERISA plans is sufficient to give rise to "reference to" preemption. *See, PCMA v. Gerhart,* 852 F. 3d 722 (8th Cir. 2017), and *PCMA v. Rutledge,* 891 F. 3d 1109 (8th Cir. 2018). [8]

Both cases involve ERISA preemption challenges to so called "MAC" laws that regulate the ability of PBMs to impose "maximum allowable cost" terms on the reimbursements they pay to dispensing pharmacies. The 8th Circuit found the laws preempted because they (i) expressly excluded self-insured ERISA plans from their coverage, and (ii) made implicit reference to ERISA plans through the regulation of "PBMs who administer or manage benefits provided by a 'covered entity,' which, by definition specifically excludes certain plans under ERISA." *Gerhart* at 729.

Both decisions rely on an earlier 8th Circuit decision, The *Prudential Insurance Company of America v. National Park Medical Center, Inc.,* 154 F. 3d 812 (8th Cir. 1998) for their direct and

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[8] The State of Arkansas has filed a Petition for Certiorari with the Supreme Court basically arguing that the 8th Circuit's holding cannot be reconciled with *Travelers.* Thirty-one states have filed as *amici* in support of the petition. The Court has asked for the views of the Solicitor General as to whether it should accept the petition.

implicit reference to ERISA analysis.[9] However, the holding in *Prudential* is inconsistent not only with holdings in other circuits dealing with similar statutory references, it also, on its face, misapplies the applicable current Supreme Court guidance as to what constitutes an impermissible reference for purposes of Section 514. A District Court in a later case dealing with an ERISA preemption challenge to a Georgia prompt pay law discussed the current status of the law as follows:

> "Because the Court concludes that IDEA has a 'connection with' ERISA plans, an inquiry into whether IDEA has a 'reference to' ERISA plans is not necessary. The Court notes, however, that IDEA does not satisfy the most recent articulations of the 'reference to' test. In earlier cases, the Supreme Court characterized the 'reference to' inquiry broadly. See, e.g., FMC, 498 U.S. at 59 (holding that a state statute that encompasses ERISA plans had a 'reference to' the plans). In later cases the Court clarified that a state law has a 'reference to' ERISA plans, and 'relates to' plans on that basis only when the law 'acts immediately and exclusively upon ERISA plans' or when 'the existence of ERISA plans is essential to the law's operation'. See, Cal. Div. of Labor Standard Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316,325 (1997)…By contrast, state laws of general application that operate 'irrespective of the existence of an ERISA plan' does not have a 'reference to' the plans….The provisions of the IDEA at issue here change the Prompt Pay Statute to apply to payments from all health plans; ERISA regulated insured plans, ERISA regulated self-funded plans, *and* non-ERISA-regulated (i.e. non-employee-based) insurance products. The amended Prompt Pay Statute functions "irrespective of the existence of an ERISA plan…It is 'indifferent to the funding, and attendant ERISA coverage of' the plans and insurance policies to which it applies. Accordingly, the 'reference to' test for determining whether IDEA 'relates to' ERISA plans likely does not apply." *America's Health Insurance Plans v. Hudgens,* 2012 WL 6735768 (N.D. Ga. Dec. 31, 2012), *aff'd* 742 F.3d 1319 (11th Cir. 2014)(holding Georgia prompt pay law to have an impermissible 'connection with' self-funded ERISA plans based on its direct impact on plan administration.)

See also, Pharmaceutical Care Management Assn. v. Rowe, 429 F.3d 294 (1st Cir. 2005) (holding state law requiring PBMs to act as fiduciaries with respect to their clients was not preempted):

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[9] The court in *Prudential* held that not only was the Arkansas law preempted by ERISA, but it also was not saved from preemption. The 8th Circuit later acknowledged that, based on the Supreme Court's new saving clause test announced in *Miller,* the law was in fact saved from preemption when applied to insured claims. *The Prudential Insurance Co. of America v. National Park Medical Center, Inc.,* 413 F.3d 897, 911 (8th Cir. 2012)

> "Although the UPDPA does operate to regulate PBMs that contract with employee benefit plans – some of which may happen to be ERISA plans – it also operates upon the state Medicaid program and on insurance companies. If the reference to employee benefit plans was deleted from the text of the UPDPA, the statute would still be operable. As we have stated previously, 'a state law that applies to a wide variety of situations, including an appreciable number that have no specific linkage to ERISA plans, constitutes a law of general application for purposes of 29 U.S.C §1144'. *Carpenters Local Union No. 26,* 215 F. 3d at 144-45 (adding that 'state laws of general application are safe from ERISA preemption)."

In other words, if self-funded ERISA plans are included within the definition of "private health care payer" under Section 6D and, therefore, would in theory benefit from the proposed legislation if they so elect, this does not mean that the proposed legislation would include an impermissible reference to ERISA plans. The law at issue in *Travelers* imposed the surcharge on patients "served by self-insured funds directly reimbursing hospitals." 514 U.S. at 650. As did the laws involved in the *Rowe* and *AHIP* decisions discussed above. In *Travelers,* the Court found that the reference to analysis could be "ruled out" because the surcharges were imposed on patients and "regardless of whether commercial coverage or membership, respectively is ultimately secured by an ERISA plan, private purchase or otherwise, with the consequence that the surcharge statutes cannot be aid to make 'reference to' ERISA plans in any manner." 514 U.S. at 656.[10] In the other two cases, relying on the Court's opinion in *Dillingham*, both courts found the laws at issue are not preempted as the laws did not act exclusively on ERISA plans, and ERISA plans were not essential to the operation of the law.

Just as the general scope of the UPL provision protects it from preemption under the "connection to" prong under *Shaw,* it should also protects it from 'reference to' preemption – the 8th Circuit's view notwithstanding.

4. Other Federal Preemption Issues

While a law that regulates what a pharmacy may charge for certain prescriptions should survive a challenge on ERISA preemption grounds, three portions of the Act as proposed could potentially run afoul of its reach. These include proposed new subsection (a) of Section 11N of Chapter 12 of the General Laws giving the Attorney General authority to obtain information from a "private health care payer" which could include ERISA plans, the changes in Ch. 12C § 10A(b) of the General Laws authorizing the Commission to request information from PBMs, and the

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[10] Both 8th Circuit decisions rely on an earlier 8th Circuit decision, The *Prudential Insurance Company of America v. National Park Medical Center, Inc.,* 154 F. 3d 812 (8th Cir. 1998), that is inconsistent with the holdings in other circuits. *See, e.g., PCMA v. Rowe and PCMA v. District of Columbia.*

requirement in Ch. 6D, § 10A(d) that requires payers to use the UPL "in developing the benefit design for such drug, including, if applicable, any cost-sharing amount."

The two provisions regarding the production of information are potentially problematic with respect to claims data and related information of self-funded ERISA plans under the Supreme Court's decision in *Gobeille v. Liberty Mutual Ins. Co.,* 577 U.S. ____, 136 S.Ct. 936 (2016) (holding the Vermont all claims payer reporting law preempted when applied to self-funded ERISA plans on "connection with" grounds based on reporting, disclosure and recordkeeping being central components of a uniform system of plan administration and the law's interference with nationally uniform plan administration).

The requirement that a payer is required to take the UPL provision into account in determining the benefit design of its ERISA plan is potentially problematic as benefit structures are core elements protected by Section 514, and a state cannot tell an ERISA plan sponsor what benefits or coverage to provide in its plan. *See, e.g., Metropolitan Life Ins. Co. v Massachusetts,* 471 U.S. 724 (1985)(state mandated benefits laws saved from preemption as laws regulating insurance, but preempted with respect to self-funded plans under the "deemer clause").

In our amended proposal, we have addressed these potential preemption issues by defining the term "private health care payer" to include self-funded plans only to the extent that such plans affirmatively elect to be subject to the Act. This approach is supported by two Courts of Appeal decisions holding that a state law does not have an impermissible connection with an ERISA plan to the extent that an ERISA plan can choose whether or not to be subject to the law. *See, Pharmaceutical Care Management Assn. v. Rowe,* 429 F.3d 294 (1st Cir. 2005) and *Pharmaceutical Care Management Assn. v. District of Columbia,* 613 F.3d 179 (D.C. Cir. 2010). Both cases involved state laws that imposed certain duties on PBMs when dealing with "covered entities" which included health benefit providers such as insurance companies and "employer health plans", which would obviously include ERISA plans. In both cases, the courts held that the provisions of the laws were not preempted to the extent that the plans could agree by contract that the PBM would not be subject to the statutory duties.

> "Although the ERISA plans can re-evaluate their working relationships with PBMs if they wish to in light of the [law], nothing in the [law] compels them to do so. This is not an instance…where the plan administrator is bound to a particular choice of rules mandated by the state…The plan administrators here have a free hand to structure the plans as they wish in Maine. We find, therefore, that the [law] does not have an impermissible 'connection with' ERISA plans.

Based on these decisions, we believe that the above opt-in provisions should create much of the sought after benefits of the UPL limitations for ERISA plans, since most can be expected to elect to take advantage of them, and should provide the basis for the Act to survive an ERISA preemption challenge.

B. Dormant Commerce Clause Interference

Under the principle against extraterritoriality established by the dormant Commerce Clause (*See* U.S. Const. Art. I, § 8 cl. 3.) , a state cannot "regulat[e] commerce occurring wholly outside that State's borders." *Healy v. Beer Institute, Inc.*, 491 U.S. 324, 332 (1989). Nor can a statute "benefit in-state economic interests by burdening out-of-state competitors." *Dept. of Revenue of Ky. v. Davis*, 553 U.S. 328, 337-338 (2008). Recent case law involving drug pricing legislation has highlighted the potential reach of the dormant Commerce Clause on a state's ability to regulate the prices of prescription drugs sold within the state. The key distinction between legislation courts have upheld as constitutional under the dormant Commerce Clause and provisions that have not survived such a constitutional challenge is whether the activity being regulated takes place within the state seeking to impose the challenged restriction. If the revisions to the UPL provisions we have proposed are enacted, we believe that the Act would be sufficiently limited to transactions occurring within the Commonwealth of Massachusetts to survive a challenge based on the dormant Commerce Clause.[11]

Two recent cases, *The Association for Accessible Medicines v. Frosh* and *Pharmaceutical Research & Manufacturers of America v. Walsh* form the basis for our conclusion. In *Frosh*, the Fourth Circuit held Maryland's anti-price gouging statute to be unconstitutional under the dormant Commerce Clause because it "directly regulate[d] transactions that take place *outside Maryland*." 887 F.3d 664, 674 (4th Cir. 2018) (emphasis in original). That statute, which went into effect on October 1, 2017, prohibited "[a] manufacturer or wholesale distributor" from "engag[ing] in price gouging in the sale of an essential off-patent or generic drug," defining "price gouging" as "an unconscionable increase in the price of a prescription drug." Md. Code Ann., Health – General § 2-802(a) [repealed]; *Id.* § 2-801(c) [repealed]. The Association for Accessible Medicines ("AAM") challenged the constitutionality of the statute based on the dormant Commerce Clause, asserting that even though the provisions of the statute were triggered only when one of the drugs regulated by the statute was available for sale in Maryland, the statute actually resulted in direct regulation of the prices charged in out-of-state transactions. *Frosh*, 887 F.3d at 670.

Although the district court upheld the statute, the Fourth Circuit agreed with AAM, finding that the statute was not limited to sales wholly within Maryland, and indeed impacted transactions occurring wholly outside of the state because "the lawfulness of a price increase is measured according to the price the manufacturer or wholesaler charges *in the initial sale of the drug*." *Id.* at 671 (emphasis in original). Because the structure of the statute clearly targeted "the upstream pricing and sale of prescription drugs," which nearly always occurred outside Maryland, the Court of Appeals held that the statute "effectively seeks to compel manufacturers and wholesalers to act

[11] Our review is focused on the dormant Commerce Clause issues associated with the UPL and accordingly does not address the mandate that the UPL be considered in benefit design.

in accordance with Maryland law outside Maryland," in violation of the Constitution. *Id.* at 671-672.

One particular challenge the court noted was the potential for "a manufacturer to consummate a transaction in a state where the transaction is fully permissible, yet still be subject to an enforcement action in another state (such as Maryland) wholly unrelated to the transaction." *Id.* at 673. In articulating this issue, the Fourth Circuit considered and rejected the district court's finding that it was merely a "practical problem" that could be addressed by, as the lower court suggested, drug manufacturers modifying their distribution systems to identify and isolated drugs bound for Maryland. *Id*. The appellate court emphasized that the statute under review went beyond requiring manufacturers and distributors to alter their distribution channels, and instead set "prescription drug prices in a way that interferes with the natural function of the interstate market by superseding market forces that dictate the price of a good." *Id.* (internal quotations omitted). It noted that drug manufacturers' compliance with the statute "would require more than modification of their distribution systems; it would force them to enter into a separate transaction for each state" and even still, would subject them to liability if a drug intended for another state were later made available for sale in Maryland. *Id.* at 673-74. Given that this type of "competing and interlocking local economic regulation" was exactly what the Commerce Clause sought to preclude, the court invalidated the Maryland statute. *Id.* at 674 (quoting *Healy*, 491 U.S. at 337).

Although Maryland petitioned the Supreme Court for certiorari, the high court declined to take up the case. Notably, in the response to the petition, AAM recognized that a state could regulate sales within the state, specifically stating that a state "could regulate in-state retail prices…" and that "the Commerce Clause does not forbid states from enacting laws that cause ripple effects beyond their borders." Brief in Opposition to Petition for Certiorari, at p. 30.

In *Walsh*, on the other hand, the Supreme Court upheld a Maine statute establishing a drug rebate program, finding that it did not violate the principle against extraterritoriality in the dormant Commerce Clause. The law at issue created the "Maine Rx" program that required any drug manufacturer selling drugs in Maine through the state's financial assistance program to enter into a rebate agreement with the state, or be subject to a prior authorization procedure for in-state Medicaid prescriptions, which resulted in lower in-state prescription prices for Maine residents participating in the program. *Walsh*, 538 U.S. 644, 654 (2003). The PhRMA organization challenged the Maine statute, in part on the basis that it violated the dormant Commerce Clause by "effectively regulat[ing] out-of-state commerce." *Id.* at 650.

In this case, the Supreme Court disagreed, upholding the statute and concurring with the First Circuit decision that "the Maine Act does not regulate the price of any out-of-state transaction, either by its express terms or by its inevitable effect. Maine does not insist that manufacturers sell their drugs to a wholesaler for a certain price [and] is not tying the price of its in-state products to out-of-state prices." *Id.* at 669 (quoting *Pharmaceutical Research and Manufacturers of America v. Concannon*, 249 F.3d 66, 81-82 (1st Cir. 2001). Given that Massachusetts is in the 1st Circuit,

this case, of course, would be the key governing case in any Federal Court Commerce Clause challenge.

As illustrated by these two cases, the critical difference affecting a state statute's compliance with the dormant Commerce Clause is whether there is a sufficient nexus between the actual activity being regulated in the regulating state, and whether the challenged regulation also has a direct impact on transactions which take place in other states. Maine's law survived a constitutional challenge because its terms were limited to regulating transactions occurring in Maine—the sale of drugs through the Maine Rx program—whereas Maryland's law impermissibly regulated upstream transactions almost always occurring outside of the state. Thus, the lesson of these two decisions is that to enhance the potential to survive a dormant Commerce Clause challenge, the commercial activity regulated by a drug pricing statute needs to be limited to transactions actually occurring in the state.[12]

Our proposed revisions to the UPL provisions limit the application of the UPL to drugs administered or dispensed to individuals within the Commonwealth of Massachusetts. As such, the statute would both make the nexus to the Commonwealth clear, but also limit its application to transactions which occur "in the state", to protect residents of the Commonwealth from excessive drug prices. Unlike the UPL provision in the original version of the proposed legislation, which would apply to all "reimbursements of the prescription drug product in the [C]ommonwealth," (e.g., a drug purchased and dispensed in another state that is reimbursed by Blue Cross Blue Shield of Massachusetts) the revised language would provide a clear connection between payment for the drug and a transaction that solely occurs in the Commonwealth.

We recognize that the vast majority of retail drug claims are processed electronically through a standardized national adjudication system, in which a prescription is presented to a pharmacy which then inputs the beneficiary's information to automatically connect to the beneficiary's PBM or other plan administrator. That system then provides information to the pharmacy regarding coverage for the drug and the amount to collect from the beneficiary, along with the payment to the pharmacy. Given this complex, national process, it is not clear exactly where "reimbursement" for the drug occurs—indeed, it could easily be interpreted to occur outside of the state where the drug was actually dispensed. To avoid an attack asserting that the regulated transaction occurs outside of the state, we have proposed a clause in Section 8 limiting wholesale and retail drug purchases which are subject to the UPL to those in which "the prescription drug

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[12] Further, to the extent that the transaction being regulated relates to the state itself as the purchaser, such as for its Medicaid program, such transactions are exempt from the application of the dormant Commerce Clause. *See Asante et al. v. Cal. Dept. of Health Care Servs.*, 886 F.3d 795 (9th Cir. 2018) (holding that the Department did not violate the dormant Commerce Clause in adopting Medi-Cal policies related to reimbursement of out-of-state hospitals because the Department was acting as a market participant, rather than a regulator, in setting reimbursement rates, much like a private insurer participating in the market).

product is administered within the [C]ommonwealth or dispensed to one or more individuals in the [C]ommonwealth in person, by mail or by other means."

A strengthened focus on an in-state transaction helps to align the bill with the statute found to be constitutional in *Walsh,* and distance it from the law struck down in *Frosh*. We believe that this limiting clause defining what purchase of the prescription drug product "in the [C]ommonwealth" means for purposes of the UPL will allow the bill to survive a constitutional challenge based on the dormant Commerce Clause. This is because the revised UPL provisions provides a stronger tie between the activity being regulated—the purchase of drugs in the Commonwealth which are administered or dispensed in the Commonwealth—to the Commonwealth itself. Further, the revised language helps to avoid the vagueness associated with determining whether reimbursement actually occurred in the Commonwealth and makes clear that the UPL applies only when the drug is actually administered or dispensed in the Commonwealth.

III. CONCLUSION

The UPL restrictions are in line with the efforts currently underway in many states to limit the high cost of drugs for their residents. To the extent that the effort to limit that cost is based on regulation of purchases which occur within the Commonwealth for drugs administered or dispensed within the Commonwealth, and do not directly regulate the activities of ERISA plans, we believe that a challenge based on a claim that the UPL impinges on the reach of ERISA, and should therefore, be preempted, or that the UPL implicates the dormant Commerce Clause of the United States Constitution, could successfully be surmounted, and the UPL provisions deemed to be within the power of the Commonwealth to enforce.

4816-7022-9655.8