The Great Divide: ERISA Integrity versus State Desire to Hold Pharmacy Benefit Managers Accountable for Pharmaceutical Drug Pricing

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This Note comments on a split circuit ruling that stems from an Iowa Court of Appeals case, Pharmaceutical Care Management Ass'n v. Gerhart, that focuses on the question, "Are state laws forcing pharmacy benefit managers (PBM) to disclose pricing data preempted by the Employee Retirement Income Security Act of 1974 (ERISA)?"[1] The Eighth Circuit, as well as the D.C. Circuit, ruled that ERISA does preempt these reporting requirements. However, other circuits, like the First Circuit, have upheld the state law reporting requirements. This recent striking down of Iowa pharmaceutical law is troubling as the ruling embraces a lack of transparency and accountability as to how PBMs and insurance companies decide their drug prices. On one side, a state's law requiring reporting disclosure to state agencies (in addition to ERISA's national reporting requirements) is argued to put an economic burden on health insurance companies. On the other side, it is argued that state law forcing health insurers to report pricing data increases accountability and does not actually affect ERISA. This Note discusses the precedent leading up to this circuit split, the sides and rationales of the split, the circuit split's implications in health insurance law, why ERISA should not preempt states' laws requiring PBMs to report their pricing methodology for certain drugs, and recommends various solutions to avoid ERISA preemption, yet hold PBMs accountable for their drug pricing methods.

1. *Circuit Splits Reported in U.S. Law Week—January 2017*, 85 U.S.L.W. (BNA) No. 28 (Feb. 2, 2017), https://www.bloomberglaw.com/document/X4E3CGKO000000 [hereinafter *Circuit Splits*].

I. INTRODUCTION

Healthcare is one of the most widely contested and fundamentally important issues of the twenty-first century. The rise of technology, advances in pharmaceuticals, and greater understanding of the human mind and body within the medical field have created a boom in the healthcare industry, sparking a variety of legislation and statutes. With these advancements came the steady and ever-rising costs of healthcare and pharmaceutical drugs.[2] Most people like consistency and want to know what they are paying for. For example, when paying for a new car, an individual will want to know how the vendor set that price and if that price is comparable and fair. If people want to know this information about cars, groceries, or other everyday items, they will also want the same information for necessary prescription drugs.[3] Unfortunately, the pricing of medications is an incredibly vague area of healthcare, and the laws, or lack thereof, surrounding pricing methodologies are not much help either.[4]

To combat the opaque drug pricing methodologies, states have tried to enact statutes requiring pharmacy benefit managers (PBMs) to report how they came up with their drug prices.[5] Unfortunately, specific federal legislation has rendered these state statutes invalid in several jurisdictions.[6] Yet, courts in other jurisdictions have upheld these state reporting requirements.[7] Therefore, the question within the healthcare and pricing methodology debate is whether state statutes that require the disclosure of pricing data and a transparent methodology for setting drug prices from PBMs are federally preempted by the Employee Retirement Income Security Act of 1974 (ERISA).[8]

This Note's analysis focuses on the circuit split arising from the Eighth Circuit's ruling in *Pharmaceutical Care Management Ass'n v. Gerhart*. This 2017 case focuses on

2. *See* Alex Kacik, *Drug Prices Rise as Pharma Profit Soars*, MOD. HEALTHCARE (Dec. 29, 2017), http://www.modernhealthcare.com/article/20171228/NEWS/171229930 (describing the rising cost of healthcare and, more specifically, the increase in drug prices and the ineffective legislation surrounding pharmaceutical companies and drug pricing).

3. David Belk, *Medications: What Your Pharmacist Won't Tell You*, TRUE COST OF HEALTH CARE (2014), http://truecostofhealthcare.org/medications/ (last visited Aug. 14, 2018). Most people do not know the price of their prescriptions until they pay for them at the pharmacy. *Id.* They might know the percentage of the cost that will be covered or the amount of co-pay the insurance company is willing to cover, but again, most people do not know the going rate for generic drugs and medications since the prices are generally not listed for the general population to see. *Id.*

4. *See generally* ERIN C. FUSE BROWN & TRISH RILEY, EMPOWERING AND PROTECTING CONSUMERS: ERISA THWARTS STATE INNOVATION, NAT'L ACAD. FOR ST. HEALTH POL'Y (2017), http://www.nashp.org/wp-content/uploads/2017/02/ERISA.pdf (arguing that ERISA is contrary to state healthcare transparency laws).

5. *Id.*

6. *Id.*

7. *See generally* Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294 (1st Cir. 2005) (upholding state reporting requirements for drug pricing methodologies); Self-Ins. Inst. of Am., Inc. v. Snyder, 827 F.3d 549 (6th Cir. 2016) (upholding state reporting requirements for tax collection purposes).

8. *Circuit Splits*, *supra* note 1.

state pricing data requirements placed on PBMs and whether ERISA invalidates those requirements.[9] The Eighth Circuit ultimately ruled that ERISA does preempt these reporting requirements following the D.C. Circuit's *Pharmaceutical Care Management Ass'n v. District of Columbia* decision.[10] However, other circuits, such as the First Circuit, have upheld the state law reporting requirements.[11] As this Note will discuss, striking down the Iowa pharmaceutical reporting law creates a troubling lack of transparency as to how PBMs determine drug prices and suppresses accountability.[12] On one side, commentators argue that state laws requiring reporting disclosures to state agencies (in addition to ERISA's national reporting requirements) put a great burden on PBMs.[13] On the other side, commentators argue that a state law forcing PBMs to report pricing data increases accountability and does not substantially affect the true spirit of ERISA.[14] This Note discusses the precedent leading up to this circuit split, the respective rationales of each side in the split, the circuit split's implications in health insurance law, and finally why ERISA should not preempt state laws that require PBMs to report their drug pricing methodologies. This Note will conclude by recommending various solutions to avoid ERISA preemption, while still holding PBMs accountable for their drug pricing methods.

II. BACKGROUND

Before delving into the complicated relationship demonstrated in *Gerhart* and of other circuits' decisions, some background information on ERISA and the evolution of state reporting requirements is necessary. In addition to covering the development of ERISA, this section will break down the rulings of several circuits and their rationales for ERISA preemption or non-preemption. Lastly, this section will cover the recent ruling of *Gerhart* and will briefly cover the ruling in *Rutledge*.

A. ERISA and Its Interaction with Healthcare

The Employee Retirement Income Security Act (ERISA) was adopted in 1974 for the purpose of protecting "'the interests of participants in employee benefit plans and their beneficiaries' by setting out substantive regulatory requirements for employee benefit plans and to 'provid[e] for appropriate remedies, sanctions, and ready access to the Federal courts.'"[15] In other words, ERISA was created to protect employee benefit plans—particularly retirement plans—from being misused by employers, insurance companies, state agencies, and similar entities.[16]

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9. Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722, 725 (8th Cir. 2017).

10. *Circuit Splits*, *supra* note 1; *see generally Gerhart*, 852 F.3d 722 (holding a statute referencing and connected to ERISA preempted); Pharm. Care Mgmt. Ass'n v. District of Columbia, 613 F.3d 179, 184–89 (D.C. Cir. 2009) (discussing at what point a state law "relates to" an employee benefit plan).

11. *See, e.g.*, *Rowe*, 429 F.3d at 313; *Snyder*, 827 F.3d at 559.

12. FUSE BROWN & RILEY, *supra* note 4, at 2.

13. Liberty Mut. Ins. Co. v. Donegan, 746 F.3d 497, 507 (2d Cir. 2014).

14. FUSE BROWN & RILEY, *supra* note 4, at 1–3.

15. *See Snyder*, 827 F.3d at 554 (alteration in original) (quoting Aetna Health Inc. v. Davila, 542 U.S. 200, 208 (2004) and 29 U.S.C. § 1001(b) (2011)).

16. *See Employee Retirement Income Security Act – ERISA*, INVESTOPEDIA, https://www.investopedia.com/terms/e/erisa.asp?lgl=rira-related-content-baseline (last visited Aug. 19, 2018) (explaining that the purpose of ERISA is that it "protects Americans' retirement assets by implementing rules that qualified plans must follow to ensure plan fiduciaries do not misuse plan assets. Under ERISA, plans must provide

When ERISA interacts with state health law and the law's price reporting requirements, ERISA's preemption provision comes into play.[17] Conflict, or obstacle, preemption is the "principle that federal or state statute can supersede or supplant state or local law that stands as an obstacle to accomplishing the full purposes and objectives of the overriding federal or state law."[18] ERISA contains a specific preemption clause that states "[ERISA] shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan."[19] The preemption clause means that when a jurisdiction decides that a state reporting law conflicts or burdens ERISA or ERISA's goals, the state law will be held invalid. The circuit split arises because different jurisdictions have different interpretations of when a state law burdens ERISA. In other words, and as will be shown through the case analysis of Section II (B), the difference in defining and interpreting the "relate to" language in the ERISA preemption clause is the reason for the split.[20]

This Note analyzes the implications of ERISA on the interactions between PBMs, pharmacies, and state laws. When a patient receives a prescription from their doctor, she will fill it at the pharmacy.[21] Normally a patient's prescription will be fully or partially covered by some sort of health insurance plan, assuming the patient is part of a health insurance plan.[22] "PBMs act as intermediaries between health plans and pharmacies."[23] Additionally,

> PBMs perform such services as processing claims, generating reports and data, and managing clinical and financial information as well as retail and mail-order drug[s] . . . To carry out these services, PBMs . . . create confidential maximum allowable cost (MAC) lists. [These] lists are used to set reimbursement rates for pharmacies filling generic prescriptions.[24]

A "maximum allowable cost" is defined as "the unit price established by the PBM for a . . . drug included on PBM's MAC drug lists developed for PBM's clients, which may be amended . . . by [the] PBM, in its sole discretion."[25] In other words, a maximum allowable cost (MAC) is a price that is established by PBMs with a PBM methodology that varies from client to client, and can be changed at the PBM's discretion.[26] It is important to keep this breakdown in mind, especially when considering the transparency concern surrounding the MAC methodology that will be discussed later.[27]

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participants with information about plan features and funding, and regularly furnish information free of charge.").

17. NAT'L ACAD. FOR STATE HEALTH POLICY, ERISA PREEMPTION PRIMER, http://www.nashp.org/wp-content/uploads/sites/default/files/ERISA_Primer.pdf (last visited Aug. 19, 2018) [hereinafter ERISA PREEMPTION PRIMER].

18. *Obstacle Preemption*, BLACK'S LAW DICTIONARY (10th ed. 2014).

19. Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1144(a) (2012).

20. *Id.*; *see also*, *infra* Part II.B.

21. Pharm. Care Mgmt. Ass'n v. Rutledge, 240 F. Supp. 3d 951, 956–57 (E.D. Ark. 2017).

22. *Id.* at 956.

23. *Id.*

24. *Id.* at 956–57 (internal citations omitted).

25. Linda Cahn, *Don't Get Caught By PBMs' MAC Mousetraps*, MANAGED CARE (Sept. 1, 2008), https://www.managedcaremag.com/archives/2008/9/don-t-get-caught-pbms-mac-mousetraps.

26. *Id.*

27. *See infra* Part III.B. (detailing the cons of ERISA preemption, but specifically referencing the lack of transparency with MAC formulas).

B. The Relevant Cases & Their Stances on ERISA Preemption of State Reporting Requirements

One of the seminal ERISA preemption cases is *New York State Conference of Blue Cross & Blue Shield v. Travelers Insurance Co*.[28] This 1995 case concerned a New York law that required hospitals to collect additional charges from those covered under commercial insurers who had employee plans under the jurisdiction of ERISA, but exempted those under Blue Cross/Blue Shield plans from the extra charges.[29] This New York law also applied these charges to Health Maintenance Organizations (HMOs) whose fees were paid for by ERISA.[30] The Supreme Court weighed whether this New York statute conflicted with ERISA to the extent that ERISA preemption would be merited.[31] In deciding this, the Court focused on the ERISA clause stating that ERISA preempts "any and all State laws insofar as they . . . [may now or hereafter] relate to any employee benefit plan."[32] The court analyzed how to properly interpret the "relate to" language within the preemption provision.[33] The Court found the language of the ERISA preemption clause frustrating since it provides little guidance on what "relates to" or what "connection with" means.[34] The court ultimately held that state laws regulating cost uniformity that have "only an indirect economic effect on the relative costs of various health insurance packages . . . do not bear the requisite 'connection with' ERISA plans to trigger pre-emption."[35] The test to be interpreted from this ruling is as follows: to avoid ERISA preemption, the disputed statute (1) has to be a state law whose main purpose is to regulate cost uniformity (for example, a uniform MAC formula for pricing pharmaceutical drugs) and (2) can only have an "indirect economic" cost burden on PBMs. To reiterate, if the statute meets these two requirements, then it will not be preempted by ERISA; as it does "not bear the requisite 'connection with' ERISA plans."[36] While the case does not explicitly deal with additional state reporting requirements, it does show the interaction between a state statute imposing costs on insurance companies and ERISA's preemption provision.[37]

The next case in the line of ERISA preemption of state statute precedent is *Pharmaceutical Care Management Ass'n v. Rowe*.[38] In this case, Pharmaceutical Care Management Association (PCMA) (which is a PBM) challenged a district court ruling to uphold Maine's Unfair Prescription Drug Practices Act (UPDPA).[39] UPDPA was enacted to hold PBMs accountable to health benefit providers and to "help control prescription drug costs and increase access to prescription drugs."[40] To provide such protection, UPDPA requires that PBMs report any "conflicts of interest, disgorge profits from self-dealing, and

28. N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995).
29. *Id.* at 649.
30. *Id.*
31. *Id.*
32. *See id.* at 651 (quoting 29 U.S.C. § 1144(a) (2012)).
33. *See Travelers Ins. Co.*, 514 U.S. at 649.
34. *Id.* at 656.
35. *Id.* at 662.
36. *Id.*
37. *See generally id.*
38. Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294 (1st Cir. 2005).
39. *Id.* at 299.
40. *Id.* at 298–99.

disclose . . . their financial arrangements with third parties."[41] In response, PCMA challenged the Act and, as one of its many claims, argued that it should be preempted by ERISA.[42] The court ultimately held that ERISA cannot preempt UPDPA because ERISA only preempts those statutes that regulate actions of fiduciaries as defined under ERISA, and UPDPA does not treat PCMA as a fiduciary.[43] While it is not the focus of this Note, this holding is important as it shows the scope of ERISA preemption. The First Circuit then goes on to explain exactly what type of state statutes ERISA does preempt.[44] First, when looking at whether ERISA preempts state law, the starting presumption is that ERISA has a more tailored meaning and should be interpreted according to congressional intent.[45] The language of ERISA is "still subject to 'the starting presumption that Congress does not intend to supplant state law'" and the Supreme Court has emphasized that "unless congressional intent to preempt clearly appears, ERISA will not be . . ." allowed to preempt the state law.[46] However, the court does state that if a statute "relates to" ERISA then it may be subject to preemption.[47] To see if a statute "relates to" an employee benefit plan under ERISA, the court asks if the state law "[1] has a connection with or [2] a reference to such a plan."[48] Under prong one, the court deems a state law to be in "connection with" an employee benefit plan (and subsequently preempted by ERISA) if the law "impede[s] [ERISA's] goal of national uniformity" in the administration of employee benefit plans.[49] The court ruled that UPDPA was not in "connection with" ERISA in this regard and therefore not preempted.[50] Under the second prong, the court reasoned that a state law "references" an employee benefit plan when the state law's operation depends on the existence of ERISA plans (i.e., the state law specifically targets ERISA plans).[51] Since UPDPA would still operate without ERISA plans, the court found that the Maine law was not in "reference to" plans under ERISA and, therefore, not preempted.[52]

Moving forward, in *Gobeille v. Liberty Mutual Ins. Co.*, the United States Supreme Court affirmed the Second Circuit's ruling in *Liberty Mutual Ins. Co. v. Donegan*.[53] Here,

41. *Id.* at 299.
42. *Id.*
43. *Rowe*, 429 F.3d at 301.
44. *Id.* at 301–05.
45. *Id.* at 301.
46. *See id.* (citing the rationale from N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645 (1995)).
47. *Id.*
48. *Rowe*, 429 F.3d at 302.
49. *Id.*
50. *Id.* at 303.
51. *Id.* at 303–04.
52. *Id.* at 304. Also note that the court found support under Carpenters Local Union No. 26 v. U.S. Fidelity & Guar. Co., 215 F.3d 136, 144–45 (1st Cir. 2000) that "state laws of general application are safe from ERISA preemption."
53. Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 943, 947 (2016). In *Donegan*, the Second Circuit reaffirmed that "state laws having only an 'indirect economic effect on ERISA plans' lack sufficient 'connection with' or 'reference to' an ERISA plan to 'trigger ERISA preemption.'" *See* Liberty Mut. Ins. Co. v. Donegan, 746 F.3d 497, 507 (2d Cir. 2014) (applying *Travelers* and quoting New England Health Care Emps. Union v. Mount Sinai Hosp., 65 F.3d 1024, 1030–33 (2d Cir. 1995)). The court also ruled that the Vermont statute, imposing additional price reporting requirements on Liberty Mutual, was preempted by ERISA because "'reporting' is a core ERISA function shielded from potentially inconsistent and burdensome state regulation." *Id.* at 508.

Vermont passed a statute that required "disclosure of payments relating to health care claims and other information relating to health care services," which was subsequently challenged by Liberty Mutual Insurance Company, claiming that ERISA should hold this statute invalid.[54] The court, drawing from the principles laid out by *Travelers* and other preceding case law, stated that ERISA preempts two types of state laws.[55] Under the first category, ERISA will preempt a state law if that law "has a 'reference to' ERISA plans."[56] Under the second category, a state law will be preempted if that law "has an impermissible 'connection with' ERISA plans, meaning a state law that 'governs . . . a central matter of plan administration' or 'interferes with nationally uniform plan administration.'"[57] The court ultimately focused on the second category.[58] The court ruled that ERISA did preempt the Vermont statute, for it encroached on "a fundamental area of ERISA regulation and thereby counters the federal purpose" of ERISA, with the "fundamental area" explicitly described as the additional state recording and reporting requirements.[59]

In *Self-Insurance Institute of America, Inc. v. Snyder*, the Sixth Circuit analyzed the issue of whether or not ERISA should preempt a Michigan statute that placed a tax on already paid healthcare claims.[60] The court held that ERISA did not preempt this statute because it "does not directly regulate any integral aspects of ERISA . . . . Though it does touch upon reporting [requirements] and record-keeping, the thrust of the Act is to collect taxes—not to amass data."[61] The court based their rationale off of tests laid out by the *De Buono* and *Travelers* courts, and then contrasted this with the *Gobeille* holding.[62] The test presented in *De Buono* and *Travelers,* as to whether ERISA should preempt a state law or not, is dependent on the type of effect the state law has on ERISA.[63] The court states that "laws necessitating incidental reporting d[o] not implicate ERISA's . . . preemption provision," noting that there is a "difference between a state law that directly regulates integral aspects of ERISA plan administration and a state law that touches on these aspects only peripherally."[64]

C. Today's Circuit Holding: Gerhart

The tale of ERISA preemption and the Act's effects on healthcare regulation comes to a head with the *Gerhart* (and *Rutledge*) ruling. The *Gerhart* case brilliantly highlights the current tension between ERISA and state reporting requirement laws.

In *Gerhart*, Iowa enacted a statute, Iowa Code Section 510B.8, requiring PBMs to report to Iowa's insurance commissioner how the PBMs calculated their pricing standards

54. *Gobeille*, 136 S. Ct. at 940.
55. *Id.* at 943.
56. *See id.* (noting that the court goes on to further explain "reference to" by quoting the *Dillingham* court: "[w]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation . . . that reference will result in pre-emption." (internal quotation marks omitted) (quoting Cal. Div. of Labor Standards Enf't v. Dillingham Constr., Inc., 519 U.S. 316, 325 (1997)).
57. *See id.* (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001)).
58. *Id.*
59. *Gobeille*, 136 S. Ct. at 946.
60. Self-Ins. Inst. of Am., Inc. v. Snyder, 827 F.3d 549, 553 (6th Cir. 2016).
61. *Id.* at 557–58.
62. *Id.* at 558.
63. *Id.* at 557.
64. *Id.*

for listed generic drugs.[65] In addition, the statute restricted PBMs from applying MAC pricing to certain types of drugs.[66] This statute further required PBMs to include how they calculated their pricing standards within their contracts with pharmacies and specify steps that pharmacies could take in order to appeal a PBM's pricing standard.[67] In response, the Pharmaceutical Care Management Association (PCMA) brought a claim arguing that ERISA preempts the Iowa Code, because the Code is in "reference to" and/or in "connection with" ERISA plans.[68] The district court ruled in favor of the State, saying that "the existence of ERISA plans is not essential to the law's operation and . . . the statute does not act 'immediately and exclusively' on ERISA plans."[69] However, the Eighth Circuit reversed the district court and held that ERISA preempted the Code, as it had an "impermissible reference to ERISA [and] ERISA plans."[70] Essentially, the court held that the Code had multiple "references to" ERISA because of the language used, including explicitly referencing ERISA.[71] Additionally, after some further digging, the court found that the Code targeted "those PBMs who administer[ed] prescription drug benefits for plans subject to ERISA regulation, and specifically exempts certain ERISA plans from its application."[72] Due to this targeting, and "reference to" ERISA, the court held that the Code was preempted by ERISA.[73] While the court did not deem it necessary to find the Code to be in "connection with" ERISA (since the Code was found to be in violation of the first prong), the court analyzed the second prong and reaffirmed concepts in *Gobeille*.[74] The court found that a state law is in "connection with" ERISA if the law regulates "fundamental aspects of ERISA."[75] The court held that the Iowa Code regulated and imposed limitations on PBMs that conflicted with ERISA's fundamental "intent of making plan oversight and procedures uniform,"[76] and would therefore be preempted by ERISA under both the first and second prongs of the court's preemption test.[77]

As previously mentioned, the tensions between state reporting requirements and ERISA preemption came to a head in the *Gerhart* case. However, it is important to remember that the *Gerhart* ruling is not the controlling rule for all jurisdictions. This Note

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65. Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722, 727 (8th Cir. 2017).

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.* at 727–28. Remember that this was the two-pronged test that the court used in *Rowe* to uphold the Maine statute.

70. *Gerhart*, 852 F.3d at 730. The court also states that "[w]here a State law is preempted because it has a prohibited 'reference to' ERISA or ERISA plans, we need not reach the question of whether it is also preempted under the 'connection with' prong of the analysis." *Id.*

71. *Id.* at 729.

72. *Id.* at 730.

73. *Id.*

74. *Id.*

75. *See Gerhart*, 852 F.3d at 730–31 (describing "fundamental aspects of ERISA" as regulation of "reporting, disclosure, and recordkeeping [that] are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA").

76. *Id.* at 731.

77. To quickly note further support for this court's holding, the *Rutledge* Court (U.S. Eastern District Court for Arkansas) came to the same ruling through similar analysis as the *Gerhart* Court. *See* Pharm. Care Mgmt. Ass'n v. Rutledge, 240 F. Supp. 3d 951, 957 (E.D. Ark. 2017) (explaining that "[t]he Southern District of Iowa and [the Arkansas] court independently reached the same conclusions when analyzing similar statutes."), *aff'd per curiam*, 891 F.3d 1109 (8th Cir. 2018).

will further discuss the impacts of this ruling and others that upheld ERISA preemption and how these rulings are problematic for pricing transparency and consistency.[78] This Note will briefly summarize the general test courts apply for ERISA preemption of state statutes, then delve into one of the pros and many of the cons of ERISA preemption as the Act stands today. After presenting both sides of ERISA preemption, this Note will recommend solutions that would successfully remedy the lack of MAC uniformity and the lack of pricing transparency and consistency, while protecting the original purpose of ERISA.

III. ANALYSIS

Through various litigation and rulings surrounding ERISA preemption of state statutes, general rules have emerged. At first it seemed as though ERISA would preempt a state statute if that statute "relates to" ERISA covered plans, and this still seems to be the case in some jurisdictions.[79] While this is quite a broad interpretation, Congress carved out exceptions for state statutes in certain areas of law.[80] In essence, if a state's statute meets the specific exception, the statute is protected from ERISA preemption, even if the statute is "relate[d] to" ERISA.[81] This wide scope was more narrowly tailored in some jurisdictions with the Court's ruling in the *Travelers* case.[82] While some jurisdictions favor the narrower *Travelers'* standard, others still opt for the broad "relates to" standard.[83] However, ERISA preemption, when broadly applied, may protect employee health insurance plans but it does not protect consumers from unfair pharmaceutical drug pricing—which is why, among other solutions, the courts should opt for the more narrow application.

A. The Positive Side of ERISA Preemption

ERISA states that it will preempt[84] "any and all State laws insofar as they may now

78. As a side note, the states did attempt to evade ERISA preemption by classifying their reporting laws as regulating "insurance," which ERISA allows for under the "deemer" clause. However, courts quickly caught on and ruled that states could not use this loophole classification (i.e., they could not claim that they were regulating insurance as a way to escape ERISA preemption). ERISA PREEMPTION PRIMER, *supra* note 17, at 3.

79. William M. Sage, *Nothing (Still) Matters: ERISA Preemption Returns to the Supreme Court*, HEALTH AFF. BLOG (Dec. 7, 2015), http://healthaffairs.org/blog/2015/12/07/nothing-still-matters-erisa-preemption-returns-to-the-supreme-court/.

80. *See id.* (noting that under §514 of ERISA, even if a state statute "relates to" ERISA it will not be preempted if the law is one regulating "insurance, banking, or securities" plans; additionally, states are not allowed to "deem . . . self-insured plans to be insurance for the purpose of regulating them." (i.e., the "deemer clause")).

81. *Id.*

82. *See id.* (explaining the ruling in *Travelers* and how a statute "that increased costs for many employee benefit plans had only an 'indirect' effect that was 'not substantial' nor 'unduly burdensome' with respect to benefit design or plan administration" was not to be preempted); *see generally* Self-Ins. Inst. of Am., Inc. v. Snyder, 827 F.3d 549 (6th Cir. 2016) (demonstrating that state laws will not necessarily be preempted if reporting requirements are not the main purpose, but merely a subsidiary of the statute).

83. Jurisdictions such as *Gobeille*, *Gerhart*, and *Rutledge* opt for the broader standard while jurisdictions like D.C. (*Rowe*) and Michigan (*Snyder*) opt for narrower language (or greater scrutiny) adopted in *Travelers*.

84. Remember that preemption is essentially one law (federal or state) overruling another law (state or local) that is impeding the purpose or success of superseding (federal or state) law. *Obstacle Preemption*, *supra* note 18.

or hereafter relate to any employee benefit plan."[85] One of the positives of allowing ERISA preemption to have such a wide scope is that the preemption protects employers from exposure to additional state reporting requirements and promotes uniformity. These preempted statutes generally attempt to impose additional requirements on PBMs to report their drug pricing methodology, but also can inadvertently harm employers that provide health care plans.[86] More specifically, the argument is that having these additional state requirements would put extreme administrative and economic burdens on employers in general.[87] Administrative and economic burdens are a concern because employer-sponsored health care systems could potentially be subjected to "as many as 50 different regulatory regimes for plan administration."[88] This is part of the reason why broad application of ERISA preemption could be seen so positively by PBMs and healthcare providers offering ERISA plans. In other words, the broad language of ERISA preemption promotes uniformity by preempting demanding, and widely varying, state reporting requirement statutes.[89]

B. The Cons of ERISA Preemption

As stated above in Part III.A., some commentators argue that ERISA preemption seems to keep costs down for employers.[90] While on its face ERISA preemption may seem to keep costs down, ERISA preemption (and, therefore, a lack of state reporting requirements) can actually be costlier for employers. This cost concern is true for state statutes that are putting reporting requirements on employers (as demonstrated in Part III.A). However, it is problematic when ERISA is preempting statutes that are requiring additional reporting from PBMs on how they calculate their drug prices. When ERISA preempts state statutes that attempt to regulate PBMs, the PBMs are free to increase prices without being held accountable.[91] Under our current healthcare system, PBMs act as third-party administrators for health plans in general but also health plans under ERISA.[92] Under these health plans, PBMs use a MAC to determine which medications should be covered under these health plans and how to price these medications.[93] The problem with this is

85. ERISA § 514(a), 29 U.S.C. § 1144(a) (2011).

86. VANESSA SCOTT, THE NEED TO STRENGTHEN ERISA PREEMPTION, AM. HEALTH POL'Y INST. 5 (2017), http://www.americanhealthpolicy.org/Content/documents/resources/The_Need_to_Strengthen_ERISA_Preemption.pdf. *See generally Gobeille*, 136 S. Ct. 936 (noting that the Secretary of Labor has authority to establish additional reporting and disclosure requirements for ERISA plans).

87. SCOTT, *supra* note 86, at 5.

88. *See id.* (raising the concern that "[a] state-by-state approach to health reform may also obligate large employers to comply with as many as 50 different regulatory regimes for plan administration.").

89. *Id.* at 6. Note that this "economic burden" argument was rejected in Self-Ins. Inst. of Am., Inc. v. Snyder, 827 F.3d 549, 556 (6th Cir. 2016) (holding that the Michigan law, taxing paid claims, did not impose administrative burdens in addition to ERISA). Another positive aspect of ERISA, as advocated by *Gerhart* and *Gobeille* specifically, is that ERISA already has reporting requirements, and by preempting various state requirements, ERISA promotes uniform reporting and uniform administration of certain healthcare plans. *See Gobeille*, 136 S. Ct. at 943 (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001)); *Gerhart*, 852 F.3d at 730–31.

90. *Supra* Part III.A.

91. FUSE BROWN & RILEY, *supra* note 4, at 1.

92. *Id.* at 2.

93. NAT'L CMTY. PHARMACISTS ASS'N, THE NEED FOR MODEL LANGUAGE REGARDING PBM "MAXIMUM ALLOWABLE COST" (MAC) REIMBURSEMENT (2014), http://www.ncpanet.org/pdf/leg/feb12/mac_onepagerfinal.pdf [hereinafter THE NEED FOR MODEL LANGUAGE].

that MAC methodology varies among PBMs, PBMs can create different MAC formulas for different clients, and it is not clear which factors are actually considered when calculating a MAC.[94] It is not possible to give a uniform example of what a MAC formula looks like because the methodology is so varied and vague.[95] Since PBMs may only cover certain medications and only a percentage of the cost of these generic drugs, network pharmacies and consumers are generally left with the costs.[96] This is particularly frustrating for pharmacies and consumers when they are stuck with expensive generic drugs without knowing how the price was calculated.[97] To combat this lack of transparency between PBMs and network pharmacies and the consumer, states have tried to implement reporting requirements for PBMs to bring their pricing methodology to light.[98] But, as we are all too familiar with at this point, ERISA generally preempts these statutes, ultimately allowing PBMs to charge generic drugs at high prices without actually needing to report why.[99] It is important to highlight one claim in Part III.A., which is that ERISA preemption is good for protecting uniformity of health care regulation.[100] This can be true in terms of protecting uniformity of employer health plans, but, again, PBMs and their pricing mechanisms are not subject to such uniformity.[101]

Another negative aspect of ERISA preemption is the lack of ERISA reporting and the prevention of state innovation. States are actively trying to combat the lack of accountability surrounding PBMs,[102] but, if the language of the statute is too specific to ERISA or if it "intrudes upon a matter central to plan administration and interferes with nationally uniform plan administration," then the statute will most likely be preempted.[103] What is interesting is that ERISA does demand PBMs to report quite a bit of data to the federal government,[104] yet PBMs are not required to "disclose the specific details of their arrangements with pharmaceutical manufacturers."[105] While ERISA calls for certain reporting requirements, it does not explicitly require PBMs to report *how* they priced their generic drugs, *how* these drugs were chosen for specific health plans, or disclose their relationships with pharmaceutical companies. ERISA also does not require PBMs to report this data to network pharmacies.[106] Furthermore, ERISA does not allow for states to fill in

94. *See* Cahn, *supra* note 25 (stating "a PBM can create different MAC lists for different clients").

95. THE NEED FOR MODEL LANGUAGE, *supra* note 93.

96. John L. Utz, *Preemption Made (Too) Easy:* Pharmaceutical Care Management Ass'n v. Gerhart, 25 ERISA Litig. Rep. (West) No. 2, at NL 2 (May 2017), https://1.next.westlaw.com/Document/I3ab252153baf11e7825baa48e37e1a4e/View/FullText.html.

97. *Id.*

98. FUSE BROWN & RILEY, *supra* note 4, at 2.

99. *See id.* at 1–3.

100. *Supra* Part III.A; SCOTT, *supra* note 86, at 1.

101. SCOTT, *supra* note 86, at 1; Cahn, *supra* note 25.

102. FUSE BROWN & RILEY, *supra* note 4, at 2.

103. *Id.*; Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 945 (2016).

104. *See* Stephen Barlas, *Employers and Drugstores Press for PBM Transparency*, 40 PHARMA. & THERAPEUTICS 206. (Mar. 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4357353/ (stating that PBMs are required to report "dispensing fees the PBM pays to a pharmacy and payments the PBM makes for ancillary administrative services such as record-keeping, data management, information reporting, formulary management, participant health desk service, benefit education, utilization review, claims adjudication, participant communications, reporting services, website services, prior authorization, clinical programs, and pharmacy audits").

105. *Id.*

106. *Id.*

these reporting gaps. When states try to enact statutes that require PBM reporting requirements, the courts hold the statutes invalid, unless the reporting requirements are an incidental part of the statute and do not directly impact ERISA in a negative way.[107] To combat against this, state legislatures are forced to choose their language in each provision of a statute very carefully (i.e., not make any reference to ERISA or anything central to ERISA), so that the whole statute will not be preempted.[108] This point will be further expanded upon in Part IV.

Another problem with ERISA preemption is that it allows PBMs to get away with practices that constitute a conflict of interest. There has been a shift from small, or community, pharmacists to PBM owned "mail-order [or] specialty pharmacies."[109] This rise in PBM-owned pharmacies is extremely problematic in the sense that it incentivizes PBMs to force "payors and consumers into using the PBM-owned mail order, specialty, or retail pharmacies" since the money will be going directly into the PBMs' pockets.[110] Consumers and pharmacies are clearly and negatively impacted by this shift in incentives.[111] Again, more often than not, when state statutes try to protect consumer patients and pharmacies against such blatant conflicts of interest on the side of the PBMs, ERISA will generally strike the statute down.[112]

There are both positive and negative aspects to ERISA preemption. While it is imperative to find a solution that respects the language of ERISA and protects employers, it is more imperative to promote transparency and hold PBMs accountable to pharmacy networks and consumers. As such, the following Part of this Note advocates for clearer federal reporting requirements that make the MAC process uniform and that hold PBMs more accountable to pharmacy networks and consumers.

IV. RECOMMENDATION

While ERISA preemption has some positive impact, the foregoing analysis shows—at least within our current system—that the negative effects outweigh the positive. As such, one proposed solution is that the circuit split should be resolved in favor of the states to allow the imposition of additional reporting requirements on PBMs. Allowing states to enact additional reporting requirements would be a great short-term solution, however, it is not the best solution in the long run.

The best long-term solution would be to create new federal regulatory legislation or to amend ERISA to create uniform pharmaceutical pricing methods, to promote transparency of PBMs' actions, and to protect the public and pharmacists from unreasonable drug pricing—since these are the main concerns of the states, pharmacies, and individual consumers. Additionally, if there is a clear uniform pricing formula, then prices will be more transparent, consistent, and predictable; easing the concerns that state

107. *See* FUSE BROWN & RILEY, *supra* note 4 (discussing the legality of PBM reporting requirements)*; See generally*, *Snyder*, 827 F.3d 549 (upholding Michigan's requirements for tax purposes because it was an incidental part of the statute).

108. Utz, *supra* note 96.

109. PBM WATCH, http://www.pbmwatch.com/conflicts-of-interest.html (last visited Oct. 20, 2017).

110. *Id.*

111. *See id.* (noting that "PBM owned mail orders often increase utilization and costs by dispensing unnecessary drugs" causing further detriment to consumers and network pharmacies).

112. *Id.*

reporting requirements were intended to remedy. Since state reporting requirements would be unnecessary under this federal legislation/ERISA amendment proposal, the litigation surrounding ERISA preemption of state reporting statutes would be alleviated as there would not be a need for state reporting statutes. This proposal would present one clear interpretation of ERISA and would alleviate the confusion of having many different statutory interpretations surrounding ERISA's interaction with state laws. While the preceding proposal is the best solution, the following section offers solutions and changes that can be implemented without altering the original language of ERISA, including necessary changes to PBM procedures, and offers solutions that involve amending ERISA.

A. Recommendations Without Altering ERISA

1. Changing State Legislative Actions

As mentioned previously, one of the main reasons why state statutes imposing additional reporting requirements are preempted by ERISA is because the state statute has language that too closely "relates to" to ERISA.[113] One solution is for state legislatures to use different language when writing reporting requirement statutes. In other words, state legislatures, at the very least, need to refrain from explicitly referencing ERISA in their statutes.[114] It would also protect state laws from ERISA preemption if legislatures made sure that their statutes are generally applicable and could essentially operate without relying on ERISA plans.[115] Instead of requiring entities under ERISA to report to state agencies, state legislatures can target entities outside the scope of ERISA.[116] Alternatively, state legislatures can make participation in additional reporting requirements voluntary.[117] While these are decent solutions, there are a few drawbacks. By making participation optional rather than required, drug companies and entities under ERISA's scope can refuse to participate. While there may be some public or social pressure to participate in such disclosure requirements, ERISA cannot force participation. Another issue with having only state reporting requirements is the lack of uniformity.[118] While these are two solutions for states, the best solutions will be achieved through either federal regulation or through amending ERISA.

2. Circuit Split Resolution in Favor of State Statutes

A second solution, and likely the easiest under our current system, would be for the

113. Sage, *supra* note 79.

114. Otherwise these state legislatures will be at risk of ERISA preemption. *See* Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722, 729 (8th Cir. 2017) (referring to the court's holding that the Iowa Code was found to be in "reference to" ERISA as it targeted ERISA plans and explicitly mentioned ERISA in the Code and was therefore found to be preempted by ERISA).

115. Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 304 (1st Cir. 2005). Also note that the court found, with support under *U.S. Fidelity & Guar. Co.*, that "state laws of general application are safe from ERISA preemption." *Carpenters Local Union No. 26 v. U.S. Fidelity & Guar. Co.*, 215 F.3d 136, 144–45 (1st Cir. 2000).

116. FUSE BROWN & RILEY, *supra* note 4, at 3.

117. *See id.* (explaining that "states can encourage voluntary participation by self-funded ERISA plans by demonstrating to employers and plan sponsors the benefits of transparency for more value-based provisions of health care for their members").

118. SCOTT, *supra* note 86, at 5 ("[A]s many as 50 different regulatory regimes [could exist] for plan administration."); *See supra* Part III (discussing the positive and negative results of ERISA preemption).

Supreme Court to interpret ERISA narrowly and allow for state reporting requirements. In other words, the Court could simply resolve the circuit spilt in favor of the state reporting requirement statutes. This is a great short-term proposal for quelling issues surrounding the lack of transparency within the MAC formulation process, and for holding PBMs more accountable for their actions. Unfortunately, this solution falls short, as there would be a complete lack of uniformity in reporting requirements, such was the concern expressed in Part III.A.[119]

B. A Long-term Proposal: Federal Regulation of PBM Actions or Amending ERISA

While the above solutions work well for the current system under ERISA, the best solution is to amend ERISA or to adopt separate federal legislation that complements ERISA and fills in its regulatory gaps. While ERISA's scope is problematic for state reporting requirements, the root of the problem—and why the states desire additional reporting requirements—is the lack of transparency and the unpredictable actions of PBMs. Again, the best solution to combat this absence of transparency is to amend ERISA or to enact federal legislation that specifies a uniform MAC pricing formula and calls for PBM pricing disclosures.

As discussed previously, PBMs use MAC methodologies to determine health plans and drug prices. The issue is that MAC methodology varies among PBMs and there is a lack of transparency as to how these methodologies are formed.[120] While ERISA does demand PBMs to disclose certain data to the federal government, ERISA likewise does not require PBMs to disclose how they calculated their drug prices, nor how they chose certain types of drugs for health plans, nor the depth of their relationships and activities with pharmaceutical companies.[121] Since states cannot fill in these reporting gaps without the risk of getting preempted by ERISA, federal regulation is necessary. This can be done in two ways: either Congress can amend ERISA and make stricter reporting requirements under the Act, or Congress can enact separate federal regulation that would complement ERISA by requiring the disclosures that ERISA originally left out. Either path would be beneficial, as the amendment/regulation would promote disclosure and pricing methodology uniformity across all PBMs. This would also address the accountability and transparency concerns of pharmacy networks and consumers.[122] Choosing the separate federal legislative path would be a great option if Congress wants to start fresh and/or if honoring ERISA as it currently stands would be easier than amending it. While federal action, whether through separate legislation or through ERISA amendments, is the best long-term solution, it is not without its challenges. In terms of legislation, enactment under this current administration might be too optimistic of an outlook, as a majority of Congress is backed by pharmaceutical companies.[123] Amending ERISA, while sharing the same goal as the separate federal regulation, would also bring similar challenges. Like the federal

119. *Supra* Part III.A.

120. Cahn, *supra* note 25.

121. Barlas, *supra* note 104.

122. Factors that the reasonable person would want to be included into the MAC formula could be any of the following: demand of the drug, supply or availability of the drug, fair market value of the drug, fair pricing in relation to the severity of the illness the drug is intended to cure or mitigate, basic price of cost of production of the drug, etc. This is clearly not an exhaustive list, but these are some factors to consider.

123. *Pharmaceuticals/Health Products: Money to Congress*, OPENSECRETS.ORG, https://www.opensecrets.org/industries/summary.php?ind=H04++ (last visited Aug. 19, 2018).

regulation path, the hardest part about amending ERISA would be getting political leaders to agree to the amendment and there would surely be pushback from big pharmaceutical companies.[124] Despite these challenges, if implemented, federal legislation would be highly successful, as it would promote transparency, accountability, and effectively cover the reporting gaps that states are not able to cover.

V. CONCLUSION

Healthcare—more specifically the rising costs of healthcare—is one of the most fundamentally important issues of the twenty-first century. It is natural that states want legislation to hold those who decide healthcare costs accountable for their methods and actions, not only for the sake of accountability, but also for the sake of transparency and fairness to the public. As mentioned at the beginning of this Note, most people would like to know that they are paying fair prices for their prescriptions.[125] Sadly, medication pricing is a very vague area of healthcare and laws, or lack thereof, surrounding pricing methodology are not much help either.[126] To combat this lack of clarity, states have tried to enact statutes requiring PBMs to report how they came up with certain drug prices; yet, as we have seen throughout this Note, some jurisdictions hold that ERISA preempts these state laws while some jurisdictions uphold the state laws.[127]

There are many solutions that can remedy the tensions between ERISA, PBMs, and reporting requirements. As a starting point, the circuit split should be resolved in favor of additional state reporting requirements. While resolving the circuit split in favor of additional state reporting requirements is a fantastic short-term solution, it is not the best solution. The best solution would be to enact federal legislation that covers the disclosure gaps of ERISA or for ERISA to be amended to include the disclosure requirements the Act originally excluded. While the "best" solution would potentially be met with opposition from pharmaceutical companies and may not survive Congress, it is the "best" solution in terms of promoting uniform reporting requirements, resolving jurisdictional differences in statutory interpretation, promoting transparency, and upholding accountability without altering the original purpose and protections of ERISA.

124. *See id.* (showing that a majority of Congress is backed by pharmaceutical companies that would likely push back on an ERISA amendment).

125. Belk, *supra* note 3.

126. FUSE BROWN & RILEY, *supra* note 4, at 1.

127. *Circuit Splits*, *supra* note 1.