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File Name: 26a0110p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

MCKEE FOODS CORPORATION,

Plaintiff-Appellee,

v.

BFP INC.,

Defendant,

CARTER LAWRENCE, in his official capacity as Commissioner of the Tennessee Department of Commerce and Insurance,

Defendant-Appellant.

No. 25-5416

Appeal from the United States District Court
for the Eastern District of Tennessee at Chattanooga.
No. 1:21-cv-00279—Charles Edward Atchley, Jr., District Judge.

Argued: December 10, 2025

Decided and Filed: April 7, 2026

Before: McKEAGUE, READLER, and DAVIS, Circuit Judges.

COUNSEL

ARGUED: Gabriel Krimm, OFFICE OF THE ATTORNEY GENERAL, Nashville, Tennessee, for Appellant. William H. Pickering, CHAMBLISS, BAHNER & STOPHEL, P.C., Chattanooga, Tennessee, for Appellee. **ON BRIEF:** Gabriel Krimm, Michael N. Wennerlund, OFFICE OF THE ATTORNEY GENERAL, Nashville, Tennessee, for Appellant. William H. Pickering, Peter A. Newman, CHAMBLISS, BAHNER & STOPHEL, P.C., Chattanooga, Tennessee, Mark E. Schmidtke, OGLETREE, DEAKINS, NASH, SMOAK & STEWART, P.C., Valparaiso, Indiana, for Appellee. Robert T. Smith, Timothy H. Gray, KATTEN MUCHIN ROSENMAN LLP, Washington, D.C., Cory L. Andrews, WASHINGTON LEGAL FOUNDATION, Washington, D.C., Deborah S. Davidson, MORGAN, LEWIS & BOCKIUS

LLP, Chicago, Illinois, Michael Kenneally, MORGAN, LEWIS & BOCKIUS LLP, Washington, D.C., for Amici Curiae.

OPINION

DAVIS, Circuit Judge. Pharmacy benefit managers—referred to in the industry as PBMs—play a pivotal role in American healthcare. They oversee prescription-drug benefits for health plans, perform administrative services, help negotiate drug rebates, and set up pharmacy networks, working with health plans, drug manufacturers, and pharmacies along the way. But the rise of PBMs has been met with state-level regulation efforts. PBMs often own pharmacies to which they steer significant business, and in the process build a significant market share of the prescription-drug benefit field in a given geographic area. Some policymakers have raised concerns that such practices can lead to the closure of small, rural pharmacies.

Citing this policy concern, Tennessee enacted laws to tamp down the PBM practice of steering patients to PBM-managed pharmacies. These laws ban interference with a patient's choice of pharmacy and restrict the provision of incentives for patients to choose certain pharmacies over others. These restrictions sweep in self-funded health plans that are governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001 *et seq.*, running headlong into that Act's preemption provision and the Supreme Court's decision in *Rutledge v. PCMA*, 592 U.S. 80 (2020). All this led to the present suit and the question we confront today: Does ERISA preempt Tennessee's PBM-focused laws? The district court thought so, and we agree. Hence, for the reasons that follow, we AFFIRM.

I.

A. Factual Background

McKee is a commercial bakery with a national presence, producing baked goods under brands such as Little Debbie and Drake's. Headquartered in Tennessee, McKee has nearly 7,000 employees, more than half of whom work in other states. McKee offers a health benefits plan ("Health Plan" or "Plan") to eligible employees. McKee and Plan participants fund the Plan,

making it a "self-funded" program governed by ERISA. Our review centers on but one of its many benefits: the Plan's Prescription Drug Program ("Program"). Under the Program, Plan participants who purchase medication from in-network pharmacies receive more favorable benefits than they would for purchasing from out-of-network pharmacies. As co-administrator of the Program, McKee plays an active role in determining the composition of the Program's approved pharmacy network.

ERISA requires every benefit plan to have a written document outlining its operation and administration. *See* 29 U.S.C. § 1102(a)(1). The Plan Document for McKee's Health Plan defines McKee as the "Plan Administrator" and the "Plan Sponsor." (Plan Doc., R. 83-1, PageID 1092; *see also* Am. Plan Doc., R. 118-1, PageID 1553). Under the Plan Document, McKee, a claims administrator, or an insurer may administer Plan benefits. It also indicates that the Plan has contracted with a PBM, which has reached agreements with pharmacies for prescription-drug services.

1. McKee's Role in Designing and Administering the Plan

McKee structured and designed the Health Plan, including the Prescription Drug Program. For example, it determined the eligibility requirements for Plan participants and established that the Program would have "different tiers of covered medications," including generic, preferred, and non-preferred brands. (Jolls Dec., R. 118-1, PageID 1544). McKee also fixed the available pharmacy benefits, varying the available options based on the medication tiers and where the medication is purchased. By McKee's design, the Plan also includes benefits for specialty medicine that treats chronic or complex conditions. On the financial front, McKee set annual deductibles, out-of-pocket maximums, copayments, and coinsurance for the Plan's various coverage options. And McKee used a PBM to provide certain administrative services for the Plan.

McKee also formed the pharmacy network from which participants may purchase medication covered by the Plan. The Program has different benefits, copays, and coinsurance depending on whether prescriptions are filled at an in- or out-of-network pharmacy. Certain pharmacies could be excluded from coverage under the Program, too. McKee and its PBM,

MedImpact Healthcare Systems, Inc. ("MedImpact"), make decisions together about inclusion or exclusion from the network or Program. All of these decisions about the Plan's networks are "extremely important" and "central to" the Plan's administration. (Jolls Dec., R. 118-1, PageID 1545).

In designing the Plan, McKee also established a preferred pharmacy network. Plan participants have lower copays on medications they purchase at pharmacies within the preferred network. McKee maintains preferred pharmacy networks in states where it does business, except Tennessee, which it attributes to "the challenged laws." (Appellee Br., ECF 26, 5). Near its Tennessee headquarters, McKee created its own pharmacy—the McKee Foods Family Pharmacy ("McKee Pharmacy")—which opened in December 2022. According to McKee, the creation, availability, and funding of its Pharmacy, along with the cost of medication purchased there, were decisions it made in designing the Plan.

2. Pharmacy Benefit Managers

Enter PBMs—the "middlemen" that oversee prescription-drug benefits for health plans. *Ohio ex rel. Yost v. Ascent Health Servs., LLC*, 165 F.4th 999, 1003 (6th Cir. 2026). PBMs leverage the prospect of high-volume exclusivity to secure lower prices for prescription drugs, contracting with several key players in the prescription-drug-benefit world. PBMs work with drug manufacturers to negotiate drug rebates, health plans to structure and manage a plan's prescription-drug benefits, and pharmacies to design pharmacy networks. *See PCMA v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023). It is these helpful services provided by PBMs that lead "most health plans [to] choose to work with" them. *Id.* Indeed, PBMs are "ubiquitous" in American healthcare; they "administer[] the drug benefits for around 270 million people"—almost "everyone with a prescription drug benefit." *Id.* at 1188–89 (citation omitted).

We focus on two perceived advantages of utilizing PBMs. *First*, plans that contract with a PBM gain access to the PBM's pharmacy network. *See id.* at 1189. With these plan relationships in place, PBMs can "contract with pharmacies to set prices and terms for beneficiary access" that pharmacies may then "package" into pharmacy networks. *Id.* From there, and "[d]epending on [its] goals," a plan can decide if it wants to "offer its beneficiaries

more or fewer pharmacy options, as tailored by the PBM's network." *Id.* Such "fine-tun[ing]" of a plan's network by a PBM allows the plan to "promote a higher quality of care" and "reduce other costs to beneficiaries, [like] insurance premiums." *Id.*

Second, PBMs help plans with lowering costs by offering "other options for refining plan networks." *Mulready*, 78 F.4th at 1189. Tiered networks—preferred and non-preferred pharmacies—are one option. *Id.* A pharmacy marked as "preferred" has struck a bargain with the PBM and the health plan: for more patient traffic, the pharmacy accepts lower reimbursements from the benefits plan. *Id.* To get that higher volume, the preferred pharmacies lower the copays required of customers. *Id.* Mail-order pharmacies offer plans an even cheaper option. *Id.* And yet another option is a specialty pharmacy that dispenses "specialty" drugs that treat chronic diseases. *Id.*

But there are perceived disadvantages to PBMs, too. For instance, PBMs frequently own and operate their own pharmacies, some of which are mail-order. *Mulready*, 78 F.4th at 1189. And PBMs regularly give their own pharmacies preferred status and label them as specialty pharmacies. *Id.* With this breadth of service, PBMs can "steer" beneficiaries to their pharmacies. *Id.* But, according to some, this steering disadvantages "non-PBM pharmacies," which (1) cannot "fill[] specialty-drug prescriptions," (2) are reimbursed at rates lower than a "drugs' wholesale price[]," and (3) are "assessed retroactive fees," among other restrictions on pharmacy practice. *Id.* at 1189–90. And say some legislators, at the local level, steering can lead to the shuttering of small rural pharmacies that are left out of the network. Such closures, in turn, can result in drug-access issues for those in the rural communities.

3. Tennessee's Laws Regulating Pharmacy Benefit Managers

From the late 1990s through the 2010s, Tennessee generally recognized that it could not regulate self-funded ERISA plans. But then came the 2020 Supreme Court decision in *Rutledge*, and with it, a perceived sea change. *Rutledge* upheld an Arkansas law regulating the reimbursement rates PBMs offered to pharmacies, holding that ERISA did not preempt the state law. 592 U.S. at 83, 85–86. Interpreting *Rutledge* as the green light it needed, Tennessee enacted Public Chapter ("PC") 569 in 2021 to gain greater oversight over PBMs. 2021 Tenn.

Pub. Ch. 569, § 2 (effective July 1, 2021). Relevant here are two provisions of PC 569. The first ("§ 3120(a)") barred PBMs and covered entities from making participants pay higher or additional copays or coinsurance when obtaining prescriptions. Tenn. Code Ann. § 56-7-3120(a) (2021). And the second ("§ 3120(b)") barred PBMs and covered entities from interfering with a patient's choice of pharmacy "in a manner that violate[d] § 56-7-2359 or by other means," which included "inducement, steering, or offering financial or other incentives." *Id.* at § 56-7-3120(b) (2021). Notably, these provisions did not target pharmacy reimbursement rates (like the law in *Rutledge*); they targeted more fundamental elements of how PBMs design benefit structures for health plans.

In July 2021, Carter Lawrence, the Commissioner ("Commissioner") of the Tennessee Department of Commerce and Insurance ("Department"), issued a bulletin about PC 569. The Commissioner announced that the new laws did not "exclude plans currently regulated by ERISA." (Bulletin, R. 119-3, PageID 1678). It was the state legislature's intent, he explained, "for ERISA plans to be included in the requirements set forth in" the new laws. (*Id.*). This meant the Department would "enforce Pub. Ch. 569 accordingly." (*Id.*). The Commissioner confirmed his belief that PC 569 regulates ERISA plans "[i]nsofar as they meet the definition of [a] 'covered entity.'" (Lawrence Dep., R. 119-4, PageID 1697).

After apparent difficulty enforcing PC 569, Tennessee enacted PC 1070. Effective January 1, 2023, PC 1070 made three relevant revisions. *First*, although it left § 3120(a) unaltered, PC 1070 revised the prohibitions against PBMs and covered entities under § 3120(b) to prevent interference with provider choice and restrict incentives that persuade patients to choose PBM-owned pharmacies. *See* 2022 Tenn. Pub. Ch. 1070 § 5 (effective Jan. 1, 2023); Tenn. Code Ann. § 56-7-3120(b). *Second*, PC 1070 expanded the definitions of "pharmacy benefits manager" and "covered entity" to include plans governed by ERISA. 2022 Tenn. Pub. Ch. 1070 §§ 3, 4 (effective Jan. 1, 2023); *see* Tenn. Code Ann. § 56-7-3102(1)(A)(xii), (5); *see also id.* at § 56-7-3122 ("Notwithstanding another law, this part applies to plans governed by [ERISA]."). *Third*, the Tennessee Legislature added language requiring PBMs to admit to their networks any willing pharmacy and precluding pharmacy favoritism. *See* 2022 Tenn. Pub. Ch. 1070 § 6 (effective Jan. 1, 2023); Tenn. Code Ann. § 56-7-3121.

Like the district court, we group these provisions into two categories: (1) the any-willing-provider ("AWP") provisions and (2) the "incentive" provisions. The AWP provisions include Tenn. Code Ann. §§ 56-7-2359, 3120(b)(1), and 3121(a) and (b).[1] And the incentive provisions include Tenn. Code Ann. §§ 56-7-3120(a), (b)(2), and 3121(c). Collectively, these are the "PBM laws."[2]

B. Procedural Background

This case began as a dispute between McKee and Defendant BFP Inc., doing business as Thrifty MedPlus Pharmacy ("Thrifty Med"), after Thrifty Med was removed from the Plan's network. Thrifty Med was a member of the Program's in-network pharmacies until an audit revealed issues with its billing practices. The audit results led McKee and MedImpact to jointly decide to expel Thrifty Med from the Plan's pharmacy network. Thrifty Med protested its removal and repeatedly sought reinstatement to the Plan. Then came PC 569.

After enactment of PC 569, Thrifty Med once again sought reinstatement to the Plan's pharmacy network. MedImpact rejected the request, prompting Thrifty Med to file three administrative complaints in the fall of 2021. All three were dismissed a short time later.[3] But soon after Thrifty Med filed its third administrative complaint, McKee filed this lawsuit, asking for declaratory and injunctive relief related to PC 569.

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[1]Section 2359, through operation of § 3120(b)(1), prohibits PBMs and covered entities from either (1) denying a licensed pharmacy the right to participate in a plan on the same terms and conditions offered to other providers under the plan or (2) preventing a party to or beneficiary of a plan "from selecting a licensed pharmacy of the person's choice to furnish the pharmaceutical services offered under any . . . plan." Tenn. Code Ann. § 56-7-2359(a)(1)–(2).

[2]The Commissioner suggests § 2359(e) is included in the PBM laws. Section 2359(e), seemingly through operation of § 3120(b)(1), requires PBMs and covered entities to apply "the same coinsurance, co-payment, deductible and quantity limit factors within the same employee group." Tenn. Code Ann. § 56-7-2359(e). Though §§ 3120(b)(1) and 2359(e) seem to also constitute "incentive" provisions, the district court omitted them from its consideration. We do the same, but note that, regardless, our analysis would remain the same. *See Frenchko v. Monroe*, 160 F.4th 784, 803 (6th Cir. 2025) ("Ordinarily, we will not address an issue not passed upon by the district court.") (citation modified).

[3]Just after PC 1070 went into effect on January 1, 2023, another Tennessee pharmacy filed an administrative complaint against MedImpact in which it claimed that McKee was utilizing lower copays to impermissibly steer patients to the McKee Pharmacy. According to McKee, this complaint remains pending.

In early 2022, the State of Tennessee intervened and moved to dismiss. By May 2022, Tennessee had enacted PC 1070. In late May 2022, McKee and Thrifty Med filed competing dispositive motions. After a hearing, the court granted Thrifty Med's motion, dismissed for lack of subject-matter jurisdiction on mootness grounds, and denied the other two motions as moot. On appeal, we reversed and remanded after concluding McKee's claims were not moot. *See McKee Foods Corp. v. BFP, Inc.*, No. 23-5170, 2024 WL 1213808 (6th Cir. Mar. 21, 2024).

Following remand, McKee amended its complaint to add Tennessee and the Commissioner as named defendants. McKee sought (1) a declaration that ERISA preempts Tennessee's PBM laws, thereby precluding their enforcement against ERISA plans and their PBMs; (2) an order enjoining enforcement of the PBM laws against McKee, the McKee Health Plan, or McKee's PBM; and (3) an order enjoining Thrifty Med from seeking reinstatement to the Plan's network.

Tennessee and the Commissioner moved to dismiss. The district court granted the motion in part, dismissing Tennessee on sovereign immunity grounds. But it denied the motion as to the Commissioner, allowing the claims against him to proceed along with those against Thrifty Med. Thereafter, McKee and the Commissioner each filed motions for summary judgment, and Thrifty Med filed alternative motions to dismiss or for judgment on the pleadings.

The district court dismissed Thrifty Med from the case, partially granted McKee's motion, and denied the Commissioner's. The court found that McKee had standing to bring a pre-enforcement challenge against the Commissioner, stated a claim upon which relief could be granted under 29 U.S.C. § 1132(a)(3), and could request equitable relief against the Commissioner. The district court also concluded that the PBM laws had an impermissible connection with ERISA plans and were therefore preempted. The district court then permanently enjoined the Commissioner from enforcing the PBM laws against McKee, "whether through direct enforcement against the Health Plan or indirect enforcement against McKee's PBM for actions taken on the Health Plan's behalf." (Op. & Ord., R. 142, PageID 2223).

The Commissioner now appeals.

II.

We review de novo the district court's resolution of the parties' cross-motions for summary judgment. *See Frenchko v. Monroe*, 160 F.4th 784, 795 (6th Cir. 2025). Summary judgment is appropriate when the evidence, taken in the light most favorable to the nonmoving party, shows there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Young v. United Parcel Serv., Inc.*, 575 U.S. 206, 231 (2015). We also "review de novo a district court's decision to grant summary judgment on the issue[] of preemption," including "[w]hether ERISA preempts a state law." *Fenner v. Gen. Motors, LLC*, 113 F.4th 585, 593 (6th Cir. 2024) (preemption generally); *Self-Ins. Inst. of Am., Inc. v. Snyder*, 827 F.3d 549, 554 (6th Cir. 2016) (ERISA preemption). We review standing determinations de novo, too. *Merck v. Walmart, Inc.*, 114 F.4th 762, 771 (6th Cir. 2024).

III.

The Commissioner begins with several threshold arguments challenging McKee's ability to bring this suit. None have merit.

A. ERISA Private Right of Action

The Commissioner argues that McKee has no private right of action and thus cannot bring a suit for a claim under ERISA. "But sometimes Congress . . . allows private parties to enforce the law through civil litigation" by creating a private right of action. *Medina v. Planned Parenthood S. Atl.*, 606 U.S. 357, 367 (2025). That is the case here.

ERISA explicitly authorizes civil enforcement actions in certain circumstances. As relevant here, ERISA creates a private right of action for "a participant, beneficiary, or fiduciary . . . to enjoin any act or practice which violates any provision of [ERISA] or the terms of the plan, or . . . to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of [ERISA] or the terms of the plan." 29 U.S.C. § 1132(a)(3). According to the Commissioner, however, this right of action does not allow McKee to bring a civil suit.

1. McKee's Fiduciary Status

The Commissioner first argues that McKee cannot maintain a private right of action under ERISA because it is suing as a plan sponsor, not as a plan participant, beneficiary, or fiduciary. McKee counters that it is a fiduciary of its health plan.

Under ERISA, every employee benefit plan must be "established and maintained" by a written instrument that designates a fiduciary with "authority to control and manage" the plan's operation and administration. 29 U.S.C. § 1102(a)(1). A plan fiduciary is one who "exercises any discretionary authority or discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets" or who "has any discretionary authority or discretionary responsibility in the administration of such plan." 29 U.S.C. § 1002(21)(A)(i), (iii); *see Briscoe v. Fine*, 444 F.3d 478, 488 (6th Cir. 2006). We "take a functional approach to ERISA fiduciary analysis," asking if any of the entity's actions "involve[] either control over plan assets or discretionary authority over plan management or administration." *Tiara Yachts, Inc. v. Blue Cross Blue Shield of Mich.*, 138 F.4th 457, 463–64 (6th Cir. 2025).

McKee meets the test for fiduciaries. True enough, McKee wears several hats, in that it is the employer, the plan administrator, and the plan sponsor. *See* 29 U.S.C. § 1002(5), 16(A), (B). Under the Plan Document, McKee administers plan benefits and holds the deciding vote on whether to allow other entities (i.e., other employers) to adopt the Plan and thereby expand the network. And McKee plays a substantial role in designing and administering the Health Plan. As one of the amici points out, ERISA plan fiduciaries have a "duty to monitor" their plans and must discharge that duty with "care, skill, prudence, and diligence." *See Hughes v. Nw. Univ.*, 595 U.S. 170, 172–73, 175 (2022) (quoting 29 U.S.C. § 1104(a)(1)(B)). McKee performed this fiduciary "duty to monitor," acting as a "prudent man" would when it removed Thrifty Med for defrauding a plan participant. *See id*. (explaining that ERISA requires a "context-specific inquiry" and noting fiduciary "duty to monitor all plan investments and remove any imprudent ones" (citing *Tibble v. Edison Int'l*, 575 U.S. 523, 530 (2015))). McKee's authority and responsibility for administering the Plan makes it a fiduciary under ERISA. *See* 29 U.S.C. § 1002(21)(A)(iii); *see also Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 317 (2016)

("Respondent, as the Plan sponsor, is both a fiduciary and plan administrator."); *Hunter v. Caliber Sys., Inc.*, 220 F.3d 702, 718 (6th Cir. 2000) (recognizing that employer plan sponsors "wear two hats: one as a fiduciary in administering or managing the plan for the benefit of participants and the other as employer in performing settlor functions"). This conclusion is bolstered by the Commissioner's answer to the amended complaint, where he expressly acknowledges that "McKee is the sponsor, administrator, *and fiduciary* of the [McKee Health Plan]." (First Am. Compl. ("FAC"), R. 83, PageID 1069, ¶ 13 (emphasis added); Commissioner Ans. to FAC, R. 117, PageID 1528, ¶ 13); *see also Ferguson v. Neighborhood Hous. Servs. of Cleveland, Inc.*, 780 F.2d 549, 550–51 (6th Cir. 1986) (observing that judicial admissions eliminate the need for evidence on subject matter of admission because the admitted fact is no longer at issue).

For its part, McKee urges us not to consider the Commissioner's private-right-of-action argument because he failed to advance it below. We resist this entreaty because "the absence of a private right of action means the district court lacked subject-matter jurisdiction." *Stew Farm, Ltd. v. Nat. Res. Conservation Serv.*, 767 F.3d 554, 566 (6th Cir. 2014). And the lack of subject-matter jurisdiction may be raised "at any stage in the litigation." *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 506 (2006). In any event, we are not persuaded by the Commissioner's contention that McKee sued only in its capacity as plan sponsor. McKee said below that it was suing as plan sponsor *and* plan fiduciary. (*See* McKee MSJ Rep., R. 139, PageID 2138). And the record substantiates its assertion. So we reject the Commissioner's assertion to the contrary.

2. Enforcing ERISA

Next, the Commissioner argues that McKee's suit fails under 29 U.S.C. § 1132(a)(3)(A) because McKee cannot show how enforcement of the PBM laws would violate ERISA.

As noted above, the ERISA private right of action allows a fiduciary to bring a civil action "(A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan." 29 U.S.C.

§ 1132(a)(3). McKee relies on both subsections, but the Commissioner focuses mostly on subsection (A).

We have not specifically held that a claim that state laws are preempted by ERISA constitutes a viable theory under which a fiduciary can sue under § 1132(a)(3)(A), though two of our sister circuits have suggested it is a permissible avenue. *See Darne v. Wisconsin*, 137 F.3d 484, 489 (7th Cir. 1998); *Denny's, Inc. v. Cake*, 364 F.3d 521, 527–28 (4th Cir. 2004). And we need not resolve that question here because, regardless of the answer, McKee's suit may proceed under § 1132(a)(3)(B)(ii).

In *US Airways, Inc. v. McCutchen*, the Supreme Court explained that "other appropriate equitable relief" as used in § 1132(a)(3)(B) "authorizes the kinds of relief 'typically available in equity' in the days of 'the divided bench,' before law and equity merged." 569 U.S. 88, 94–95 (2013) (citation omitted). Because injunctions were a kind of relief "typically available in equity," they are a type of equitable relief available under § 1132(a)(3)(B). *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 256 (1993) (emphasis omitted); *see CIGNA Corp. v. Amara*, 563 U.S. 421, 440 (2011). That includes injunctions against government officials. *See Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326–27 (2015) (explaining the "long history of judicial review of illegal executive action"). And, regardless, even if ERISA did not provide this private right of action, McKee could sue the Commissioner under the "long recognized," court-created "ability to sue" when "an individual claims federal law immunizes him from state regulation." *Id.* (citing *Ex parte Young*, 209 U.S. 123, 155–56 (1908)). ERISA does not preclude McKee's request for equitable relief through this avenue. *Cf. id.* at 327–29.

In letters submitted pursuant to Federal Rule of Appellate Procedure 28(j), the Commissioner cites two of our recent decisions, *Smith v. Michigan Department of Corrections*, 159 F.4th 1067 (6th Cir. 2025), and *Stovall v. Jefferson County Board of Education*, 164 F.4th 554 (6th Cir. 2026), to argue that (1) until the court explicitly recognizes a cause of action, one does not exist, and (2) McKee needs a separate right of action—apart from the Declaratory Judgment Act—to seek declaratory relief. Neither case moves the needle for the Commissioner. Courts have long recognized that ERISA creates a cause of action. *See Franchise Tax Bd. of California v. Constr. Laborers Vacation Tr. for S. California*, 463 U.S. 1, 27 n.31 (1983)

(acknowledging that "[s]ection 502(a)(3)(B) of ERISA has been interpreted as creating a cause of action for a declaratory judgment."); *Bluecross Blueshield of Tenn., Inc. v. Nicolopoulos*, 136 F.4th 681, 688–89 (6th Cir. 2025). And, while it is true that the Declaratory Judgment Act does not *create* a right (or cause) of action, *Davis v. United States*, 499 F.3d 590, 594 (6th Cir. 2007) (citing *Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950)), as explained above, McKee has a right to pursue an ERISA-based preemption claim against the Commissioner via other avenues such as the long-established right to pursue equitable relief against a state official, so McKee can seek declaratory relief. *See Armstrong*, 575 U.S. at 326–27; *see also Franchise Tax Bd. of California*, 463 U.S. at 27 n.31.

B. Jurisdiction

The Commissioner next argues that even if ERISA provides a private right of action for McKee, three separate jurisdictional doctrines—standing, ripeness, and sovereign immunity—stand as additional barriers to McKee's lawsuit.

1. Standing

The Commissioner argues that McKee has no standing to sue because McKee cannot show there is an imminent threat of the Commissioner enforcing the PBM laws against it. We do not agree.

Standing is a "prerequisite to federal jurisdiction." *Yoder v. Bowen*, 146 F.4th 516, 522 (6th Cir. 2025). It requires showing (1) an injury in fact, (2) that is traceable to the defendant's complained-of actions, and (3) is redressable by the court. *See id.* at 522–23. We focus on injury in fact, which requires a plaintiff to show that it has "suffered an actual past injury, or will suffer imminent future injury, that is concrete and particularized." *Id.* at 522 (citation omitted). To show an "imminent future injury" in a pre-enforcement challenge (such as this one), a plaintiff must establish four requirements: "(1) 'an intention to engage in a course of conduct' that is (2) 'arguably affected with a constitutional interest' but (3) is 'proscribed by a statute,' and (4) that there is 'a credible threat of prosecution' under that statute." *Id.* at 523 (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014)).

McKee has shown that it intended to engage in a course of conduct arguably affected with a constitutional interest and proscribed by statute (satisfying the first three *Yoder* pre-enforcement elements). McKee sought to dictate which pharmacies could be included within—or, in the case of Thrifty Med, excluded from—its plan, which would limit beneficiaries' choices and conflict with the AWP laws. Tenn. Code. Ann. § 56-7-3120(b)(1). And McKee also engaged (or intended to engage) in other conduct proscribed by the PBM laws. For example, McKee created its own pharmacy to offer beneficiaries lower copays for prescription drugs, but this element of its Plan violated Tennessee's prohibition on "[o]ffer[ing] financial or other incentives to a . . . beneficiary to persuade the . . . beneficiary to utilize a pharmacy owned by . . . the . . . covered entity" (which, in this case, was McKee). *Id.* at § 56-7-3120(b)(2). This incentivization to use the McKee Pharmacy has led to at least one administrative complaint against MedImpact. So the record supports the district court's finding that "McKee intends to act—and indeed is already acting—in a manner proscribed by the challenged laws." (Op. & Ord., R. 142, PageID 2214). And McKee's conduct is affected with a constitutional interest by virtue of its federal preemption claim, which is "basically constitutional in nature" because it "deriv[es] its force from the operation of the Supremacy Clause." *See Douglas v. Seacoast Prods., Inc.*, 431 U.S. 265, 271–72 (1977); *see also Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 388 (2000); *Torres v. Precision Indus., Inc.*, 938 F.3d 752, 755 (6th Cir. 2019). At bottom, the success of McKee's claim relies on constitutional protections and the constitutionality of the Commissioner's conduct.

The fourth pre-enforcement element—credible threat of prosecution—is satisfied, too. A plaintiff like McKee can show a "credible threat of prosecution" if it "point[s] to some combination" of the four *McKay* factors: (1) "a history of past enforcement"; (2) "receipt of enforcement warning letters regarding their specific conduct"; (3) "an attribute of the challenged statute that makes enforcement easier or more likely, such as a provision allowing any member of the public to initiate an enforcement action"; and (4) whether the defendant has "disavow[ed] enforcement of the challenged statute against a particular plaintiff." *Yoder*, 146 F.4th at 524–25 (quoting *McKay v. Federspiel*, 823 F.3d 862, 869 (6th Cir. 2016) (ellipsis omitted)). "A plaintiff need not satisfy all the *McKay* factors to establish a credible threat." *Id.* at 525 (citing *Christian Healthcare Ctrs., Inc. v. Nessel*, 117 F.4th 826, 848 (6th Cir. 2024)).

McKee has satisfied a sufficient combination of the *McKay* factors to illustrate a credible threat of enforcement. The first factor—a history of past enforcement—favors McKee because the lodging of previous complaints against a plaintiff can show a history of past enforcement. *See Driehaus*, 573 U.S. at 164. There were four administrative complaints here, three by Thrifty Med and one by a competitor of McKee's. That the Department dismissed Thrifty Med's three complaints and only one remains pending is a consideration in this holistic analysis. *Id.* (explaining that "the threat" of future enforcement "is even more substantial" when the government has actually taken adverse action due to previous complaints based on the same or similar conduct). Nonetheless, complaints are the initial stage of enforcement actions, and in our attempt to determine whether the threat of enforcement is "chimerical," these complaints show that McKee's conduct has led to preliminary enforcement activity. *See id.* (quoting *Steffel v. Thompson*, 415 U.S. 452, 459 (1974)); *cf. Steffel*, 415 U.S. at 459 (recognizing that harm comes from the threat of *prosecution*, not just the threat of the ultimate sanction). So the first factor points toward a threat of enforcement against McKee.

The second factor favors the Commissioner. There is no evidence McKee ever received an enforcement warning letter from the Commissioner about McKee's specific conduct. *Yoder*, 146 F.4th at 524.

The third and fourth factors, however, also fall in McKee's corner. The third factor considers whether the PBM laws have a feature making it easier to enforce them. They do. As written, the PBM laws permit any member of the public to initiate administrative proceedings against any PBM or covered entity for violations of the laws. *See* Tenn. Code Ann. §§ 56-7-3101(b)(1)(C), 56-7-3110. This makes the laws easier to enforce; "[b]ecause the universe of potential complainants is not restricted to state officials who are constrained by explicit guidelines or ethical obligations, there is a real risk of complaints from [competitors]." *Driehaus*, 573 U.S. at 164. The fourth factor considers whether the Commissioner has disavowed enforcement of the PBM laws against McKee specifically. *Yoder*, 146 F.4th at 524–25. He has not. Indeed, the Commissioner has, time and again, indicated that he and his Department will enforce the PBM laws against ERISA plans—going as far as to single them out in at least two letters and a response to public comments. Thus, looking across the *McKay*

factors, McKee has demonstrated a threat of enforcement. And with each sub-element of injury-in-fact established, McKee has standing; this injury is attributable to the Commissioner, and an injunction would provide redress.

The Commissioner offers four counters that fail to persuade. *First*, the Commissioner argues that the district court failed to identify anything in the record indicating he wants to block McKee from incentivizing its employees to use the company pharmacy, pointing to the pharmacy's continued operation for two-plus years before the district court's summary-judgment decision. But there is more to this than meets the eye. The McKee Pharmacy opened in December 2022, while the first round of dispositive motions in this case was pending. The district court dismissed the case in February 2023, we resolved the appeal of that dismissal in March 2024, and McKee amended its complaint in June 2024. By late January 2025, the parties had fully briefed another round of dispositive motions—including an argument by the Commissioner that there was no credible threat of prosecution. The district court resolved these motions in late March 2025, and the parties have awaited our resolution of this appeal. These procedural events explain why the record evidence does not reflect any threats of prosecution against McKee's Tennessee pharmacy—making such a threat while an argument about the lack of threats was pending would have undermined the Commissioner's efforts to dismiss the case.

Second, the Commissioner asserts that the district court considered McKee's operation of the company-owned pharmacy to be the foundation for McKee's claims—even though McKee did not offer this as a basis "for its claims *either* when it sued Thrifty *or* when it sued Commissioner Lawrence." (Appellant Br., ECF 19, 23). When McKee filed its initial and amended complaints, says the Commissioner, the Pharmacy was "not the locus of its claims," and it was inappropriate for the district court to "retroactively generate standing" on that basis. (*Id.* at 23–24 (citation omitted)). We view this as a stretch of the district court's analysis. In full context, the district court referred to the operation of the company-owned pharmacy in explaining how McKee and its PBM's conduct met the first three parts of the pre-enforcement standing inquiry that became relevant once the Commissioner was added to the lawsuit. *See McKee Foods Corp.*, 2024 WL 1213808, at *4 ("[T]he parties do not dispute that an actual case and controversy existed at the outset of the litigation."); *see also Lester v. Wow Car Co., Ltd.*,

675 F. App'x 588, 593 (6th Cir. 2017) (citing *In re Kent Holland Die Casting & Plating, Inc.*, 928 F.2d 1448, 1450 (6th Cir. 1991), for the proposition that "an amendment adding a new party creates a new cause of action"); *cf. Bare v. Cardinal Health, Inc.*, No. 22-5557, 2023 WL 395026, at *2 ("[A] plaintiff's standing must be assessed anew any time he seeks to amend his complaint." (citing *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473–74 (2007)). Moreover, the Commissioner's contention that the amended complaint does not mention the McKee Pharmacy overlooks the fact that McKee attached its Plan Document—which references the Pharmacy throughout—to its amended complaint. And written instruments attached to a pleading become part of the pleading. *See* Fed. R. Civ. P. 10(c). Besides, among the many provisions of Tennessee's PBM laws referenced in the amended complaint, McKee specifically cites the provision limiting its ability to steer beneficiaries to its Pharmacy, claiming that the provision "interferes with McKee's right to design and structure its ERISA Health Plan." (FAC, R. 83, PageID 1077–78).

Third, the Commissioner argues that the district court failed to "cabin its merits analysis to fit its theory of jurisdiction." (Appellant Br., ECF 19, 25). He contends that the only relief the district court could give McKee had to relate to the lower copays at its company-owned pharmacy, with respect to the incentive provisions. This too narrowly construes the district court's decision. True, before discussing the copay issue, the district court noted McKee's failure to include an interested pharmacy in the network. But in so doing, the district court did not limit this case to an issue about the McKee Pharmacy; it was instead demonstrating that McKee took actions, or wanted to take actions, that could be or were precluded by the PBM laws.

Fourth, the Commissioner broadly contends that "McKee and the district court have viewed this suit as an open-ended, abstract challenge to multiple statutory provisions" instead of a "real case or controversy" about the Commissioner's "enforcement of some specific legal rule against McKee." (Appellant Rep. Br., ECF 36, 11 (citation modified)). He says that an appropriate claim for relief would seek an injunction prohibiting the Commissioner from enforcing a "discrete legal provision" against McKee in a "tangible way." (*Id.* at 12). But McKee's amended complaint requested just that. It limited its request to an injunction barring

the Commissioner from enforcing §§ 3120, 3121, and 2359 against McKee, the Plan, or its PBM, or from otherwise forcing McKee or its PBM to include any pharmacy in its network. The basis for that request is McKee's assertion that ERISA preempts each of those sections of the PBM laws, and McKee based these claims on the ways these sections impacted McKee's Health Plan. The district court obliged—it declared those three sections of the PBM laws preempted and limited the relief to enjoining the Commissioner from enforcing them "against McKee's Health Plan." (Op. & Ord., R. 142, PageID 2231–32). The court's limitation included "direct enforcement against the Health Plan" plus "indirect enforcement against the Health Plan's PBM for actions the PBM takes on the Health Plan's behalf." (*Id.* at PageID 2232).

Finally, we address the third-party standing argument, raised in amici briefing, that McKee lacks standing because the Tennessee laws regulate PBMs—not McKee. That portrayal cuts too fine a distinction. Both PBMs and plan sponsors like McKee are the "object[s]" of Tennessee's regulations because the laws impose requirements on the entities that design and administer pharmacy benefit networks. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992). As detailed above, those requirements dictate how McKee structures and administers its plan, operating directly on McKee in its roles as plan sponsor and fiduciary and, independently, as the owner of an in-house pharmacy. That PBMs are also injured by these laws does not negate McKee's own injury. *Cf. Lathfield Invs., LLC v. City of Lathrup Vill.*, 136 F.4th 282, 294 (6th Cir. 2025) (explaining there is no third-party standing if the plaintiff was not injured in his own right and lacked a close enough relationship to the third party).

2. Ripeness

The Commissioner's ripeness argument is intertwined with his standing argument. *See Carman v. Yellen*, 112 F.4th 386, 400 (6th Cir. 2024) ("The constitutional elements of ripeness encompass traditional parts of the standing inquiry."). To be ripe, a case must not be "dependent on contingent future events that may not occur as anticipated, or indeed may not occur at all." *Trump v. New York*, 592 U.S. 125, 131 (2020) (citation modified). Indeed, ripeness is mainly concerned with "whether a plaintiff is threatened with imminent injury in fact." *Carman*, 112 F.4th at 400 (citation modified). And for the reasons already explained, McKee has shown a threat of imminent injury in fact. *See id.*; *Norton v. Ashcroft*, 298 F.3d 547, 554 (6th Cir. 2002)

("For pre-enforcement challenges, a case is ordinarily ripe for review only if the probability of the future event occurring is substantial and of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." (citation modified)). Additionally, as there are no "important future intervening events, such as impending regulatory action[s] [that] will clarify the dispute or obviate the need for weighing in" on the question of preemption, McKee's suit is ripe for our review. *Carman*, 112 F.4th at 400.

3. Sovereign Immunity

Lastly, the Commissioner argues that he is entitled to sovereign immunity because McKee does not seek prospective relief from a specific and imminent use of government authority. Not so.

Ex Parte Young, 209 U.S. at 123, establishes "an important limit" on and exception to a state official's sovereign immunity protections. *Virginia Off. for Prot. & Advoc. v. Stewart*, 563 U.S. 247, 254 (2011). McKee's suit meets the conditions of *Ex Parte Young*: (1) "the complaint alleges an ongoing violation of federal law," and (2) it "seeks relief properly characterized as prospective." *League of Women Voters of Oh. v. Brunner*, 548 F.3d 463, 474 (6th Cir. 2008) (citation modified). For this inquiry, we focus on the complaint's allegations only and do not analyze the claim's merits. *Id.* McKee alleged that the PBM laws violate ERISA by effectively preventing McKee from carrying out its fiduciary responsibilities required by federal law, administering its pharmacy network, and determining benefits and providers. And, McKee contended, the PBM laws also violate ERISA by interfering with plan structure and disrupting national uniformity among plans by restricting copayments and other financial inducements. These are allegations of ongoing violations of federal law (ERISA) sufficient to satisfy *Ex Parte Young*'s first condition, as the Commissioner is the state official charged with enforcing the laws in question. Tenn. Code Ann. §§ 56-7-3110, 56-2-305; *see also Whole Woman's Health v. Jackson*, 595 U.S. 30, 39, 45–46 (2021). And the relief McKee seeks—declaratory and injunctive relief—satisfies the second. *League of Women Voters of Oh.*, 548 F.3d at 474.

IV.

A. ERISA Preemption—The PBM laws "relate to" ERISA

Having resolved these threshold issues, we now turn to the merits: Does ERISA preempt the Tennessee PBM laws that McKee has challenged?

Congress enacted ERISA to "make the benefits promised by an employer more secure by mandating certain oversight systems and other standard procedures." *Gobeille*, 577 U.S. at 320–21. Its aim was uniformity among those systems and procedures. *Id.* at 321. Otherwise, "requiring ERISA administrators to master the relevant laws of 50 States and to contend with litigation would undermine" Congress's mission of "minimizing the administrative and financial burdens on plan administrators." *Id.* (citation modified).

ERISA contains an express preemption clause, which provides that ERISA "supersede[s] any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). For a state law to "relate to" an ERISA plan, and thus be preempted, the state law must have either an impermissible "connection with" the plan or a "reference to" it. *Rutledge*, 592 U.S. at 86. Because the Commissioner's main focus is the "connection with" prong, the district court analyzed only that prong, and because we conclude that the PBM laws have an impermissible connection with ERISA, we likewise limit our analysis to that prong.

"Connection with" preemption focuses on "the nature of the effect of the state law on ERISA plans." *Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 325 (1997). Relevant here, there are four bases for finding that a state law has an impermissible connection with ERISA. *First*, a state law has an impermissible connection with ERISA if it either requires "providers to structure benefit plans in particular ways," *Rutledge*, 592 U.S. at 86–87, or "prohibits employers from structuring their employee benefit plans" in a certain manner, *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 97 (1983). *Second*, if the state law "bind[s] plan administrators to [a] particular choice" about a plan's substantive benefits, it has an impermissible connection with ERISA. *Rutledge*, 592 U.S. at 87 (quoting *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 659 (1995)). *Third*, there is an impermissible connection with ERISA if the state law "governs a central matter of plan

administration." *Id.* (quoting *Gobeille*, 577 U.S. at 320). And *fourth*, when a state law "interferes with nationally uniform plan administration" it has an impermissible connection with ERISA. *Id.* (quoting *Gobeille*, 577 U.S. at 320). That said, ERISA will not preempt a state law simply because it "increase[s] costs or alter[s] incentives for ERISA plans," unless the law forces the "adopt[ion] [of] any particular scheme of substantive coverage." *Id.* at 88.

The Commissioner focuses on the second basis, arguing that the PBM laws do not bind administrators to particular choices about substantive plan benefits. But the PBM laws meet the other three bases: They require particular plan structures, govern a central matter of plan administration, and interfere with nationally uniform plan administration. So the PBM laws have an impermissible connection with ERISA.

1. Any-Willing-Provider Provisions

We begin with Tennessee's AWP provisions, which include Tenn. Code Ann. §§ 56-7-2359, 3120(b)(1), and 3121(a) and (b). Section 3120(b)(1) prohibits PBMs or covered entities from "interfer[ing] with" a participant or beneficiary's right "to choose a contracted pharmacy or contracted provider of choice in a manner that violates § 56-7-2359." *Id.* at § 3120(b)(1). Section 2359, in relevant part and when paired with § 3120(b)(1), prohibits PBMs and covered entities from either (1) denying a licensed pharmacy the right to participate in a plan "on the same terms and conditions as are offered" to other providers under the plan or (2) "[p]revent[ing]" plan participants "from selecting a licensed pharmacy of [their] choice to furnish the pharmaceutical services offered." *Id.* at § 2359(a)(1)–(2).

Then are the provisions in § 3121. Section 3121(a) says that PBMs "shall allow" participants and beneficiaries of a plan served by the PBM to use "any" Tennessee-licensed pharmacy for prescription medication, "as long as the pharmacy is willing to accept the same terms and conditions" established by the PBM for a pharmacy network it established to "serve patients, participants, and beneficiaries within th[e] state." *Id.* at § 3121(a). And § 3121(b) provides that although a PBM may establish preferred and non-preferred pharmacy networks, it cannot preclude a Tennessee-licensed pharmacy from participating in either type of network if it

is "willing to accept the same terms and conditions" the PBM established for other participating pharmacies in the network. *Id.* at § 3121(b).

The AWP provisions have an impermissible connection with ERISA because they require McKee to structure its plan in a particular way, they govern a central matter of plan administration, and they interfere with nationally uniform plan administration. *Rutledge*, 592 U.S. at 86–87. One of the main advantages of utilizing a PBM is gaining access to its pharmacy network. *Mulready*, 78 F.4th at 1189. In designing and administering benefits, a plan can decide things like the number of pharmacies it wishes to offer beneficiaries. *Id.* "[T]ailor[ing]" the network in this way gives the plan the ability to "promote a higher quality of care" while reducing beneficiaries' other costs, like insurance premiums. *Id.* Some "other options for refining plan networks," like utilizing preferred networks or mail-order pharmacies, can provide further cost-saving. *See, e.g.*, *id.* at 1189, 1199.

The AWP provisions seek to upend this structure by requiring PBMs to admit all pharmacies to a preferred network. That, in turn, requires a plan to be designed in a particular way. ERISA prohibits this. *Rutledge*, 592 U.S. at 86–87. By requiring a particular structure, the PBM laws also attempt to govern a central matter of plan administration: the scope and extent of a plan's pharmacy network—yet another indication that the state laws are preempted. *Id.* at 87. And the PBM laws disrupt "nationally uniform plan administration" because they require plans to tailor benefits in ways specific to Tennessee, once more crossing the preemption line. *Id.* Imagine other states adopting similar AWP provisions, each with slight variations from the other. Such a patchwork of laws would require plans to "maintain a familiarity with the laws of all 50 States so that they can update their plans as necessary to satisfy the [any-willing-provider] requirements of other, similar statutes." *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 151 (2001). Plans would also have to "be attentive to changes in the interpretations of those statutes by state courts." *Id.* This sort of "tailoring of plans and employer conduct to the peculiarities of the law of each jurisdiction is exactly the burden ERISA seeks to eliminate." *Id.* (citation modified). So we affirm the district court's preemption determination as to the AWP provisions.

Doing so is consistent with our decision in *Kentucky Ass'n of Health Plans, Inc. v. Nichols*, 227 F.3d 352 (6th Cir. 2000), *aff'd sub nom. Kentucky Ass'n of Health Plans, Inc. v. Miller*, 538 U.S. 329 (2003). There, we held that ERISA preempted two AWP statutes in Kentucky (though they were ultimately saved under ERISA's saving clause, as discussed in Section IV.B). *Id.* at 357–63, 372. Like the AWP provisions here, the Kentucky laws prohibited discriminating against providers "willing to meet the [plan's] terms and conditions for participation." *Id.* at 355. Though Kentucky's laws "did not operate directly on ERISA plans," they in effect required plans to "purchase benefits of a certain structure." *Id.* at 362. This, in turn, bore "indirectly but substantially" on all plans, leading us to conclude that the Kentucky laws "did more than just indirectly affect the cost of ERISA plans"—they "mandated benefit structures." *Id.*; *see also Travelers*, 514 U.S. at 668 (noting state laws with "indirect[] economic effects" "might" be preempted if they "effectively restrict [an ERISA plan's] choice of insurers"). Kentucky's laws "affect[ed] the benefits available by increasing the potential providers" and "directly affect[ed] the administration of the plans." *Nichols*, 227 F.3d at 363. So we deemed Kentucky's AWP laws preempted because they were "'connected with' ERISA covered plans." *Id.* at 363, 372.

As with the laws in *Nichols*, Tennessee's PBM laws prohibit PBMs and covered entities—like McKee, the McKee Health Plan, and MedImpact—from discriminating against any provider willing to accept the same terms and conditions established by the PBM for its other participating pharmacies. Tenn. Code Ann. §§ 56-7-2359(a), 3120(b)(1), 3121(a)–(b). The Commissioner takes the position that the PBM laws neither "prevent the construction of pharmacy networks," nor "dictate what pharmacies must be included in such networks." (Appellant Br., ECF 19, 34). But we agree with the district court that the AWP provisions "eliminate [any] choice" in how a plan structures and designs the benefits it offers by mandating pharmacy inclusion. (Op. & Ord., R. 142, PageID 2220). Though the PBM laws may not outright identify the pharmacies that must be included in a network, they improperly remove control from the ERISA plans; under Tennessee's AWP provisions, any pharmacy will be included in an ERISA plan's network so long as it will accept the network's terms and conditions. *See Associated Builders & Contractors v. Mich. Dep't of Lab. & Econ. Growth*, 543 F.3d 275, 281 (6th Cir. 2008) ("A state law has an impermissible connection with an ERISA

plan if it directly regulates or effectively mandates some element of the structure or administration of employers' ERISA plans." (citation modified)). ERISA plans cannot dictate the size and scope of their health plan networks under the Tennessee laws; this is the type of "impermissible connection" that ERISA's preemption clause sought to prevent.

The Tenth Circuit's decision in *Mulready* reinforces our analysis. There, Oklahoma enacted a swath of laws regulating PBMs, including an AWP provision. *Mulready*, 78 F.4th at 1191. Oklahoma's AWP statute barred PBMs and their agents from denying providers the chance to participate in a preferred-status pharmacy network so long as they would accept the PBM-established terms and conditions "for other providers as a condition of preferred" status. *Id.* (citation omitted). Relying in part on *Nichols*, the Tenth Circuit held that the AWP provision (and two others) "succumb[ed] to ERISA preemption." *Mulready*, 78 F.4th at 1197–99. The Oklahoma laws mandated a certain benefit structure by excluding one method of structuring benefits. *Id.* at 1198. By working in tandem with a provision that "dictate[d] which pharmacies [had to] be included" in a network, Oklahoma's AWP provision "require[d] that those pharmacies be invited to join the PBM's preferred network." *Id.*

So too here. As explained above, the AWP provisions mandate a specific benefit structure by eliminating the option for plans to set up a limited pharmacy network. Just as the Tenth Circuit determined ERISA preempts Oklahoma from implementing this type of regulatory structure, we do the same for Tennessee.

The Commissioner resists this conclusion on several grounds. He contends that we should disregard *Nichols* because (1) its discussion of "connection with" preemption was dicta, and (2) it is factually distinguishable. Neither ground is convincing.

As an initial matter, we may forgo consideration of the Commissioner's dicta argument, because he did not raise it below. *See Bannister v. Knox Cnty. Bd. of Educ.*, 49 F.4th 1000, 1011 (6th Cir. 2022) (explaining that "a party has forfeited an argument when the party belatedly asserts it on appeal after having failed to raise it in the district court."). Under appropriate circumstances, we can excuse such a forfeiture in the ends of justice. *See Berkshire v. Dahl*, 928 F.3d 520, 530–31 (6th Cir. 2019). But no such circumstances are present here.

At any rate, the Commissioner's argument is unpersuasive. While "the line between a holding and dictum is not always clear," *Freed v. Thomas*, 976 F.3d 729, 738 (6th Cir. 2020) (quoting *Metro. Hosp. v. U.S. Dep't of Health & Hum. Servs.*, 712 F.3d 248, 274 (6th Cir. 2013) (McKeague, J., dissenting) (citation modified)), "a 'holding' is 'a court's determination of a matter of law pivotal to its decision," *id.* (quoting *United States v. Hardin*, 539 F.3d 404, 438 (6th Cir. 2008) (Batchelder, J., concurring in part and dissenting in part) (citation modified)). *Nichols*'s discussion of "connection with" preemption was pivotal to the ultimate conclusion as to whether the Kentucky laws at issue were valid, so it was a holding. And, even if the *Nichols* preemption discussion were dicta, we could—and would—consider it as persuasive authority. *See BDT Prods., Inc. v. Lexmark Int'l, Inc.*, 602 F.3d 742, 750–51 (6th Cir. 2010) (noting that while dicta may be nonbinding on future panels, it still may be followed as persuasive authority).

Nor is *Nichols*'s applicability diminished by the fact that it involved physicians instead of pharmacists. Both physicians and pharmacists provide personalized healthcare services. True, pharmacists "generally dispense identical prescription-drug products." (Appellant Br., ECF 19, 39). But they also provide individualized guidance to patients on how to use those pharmaceuticals. So this is a distinction without a difference for purposes of the preemption analysis. Whether a health maintenance organization (as in *Nichols*) or a PBM (as here), both types of entities perform certain functions for ERISA health benefit plans. So the ultimate question remains the same: Is it permissible for a state to enact laws that encroach on the discretion bestowed on plans to structure and design them as they see fit? As we answered above, ERISA prevents such state-level interference with ERISA plan autonomy. *See Rutledge*, 592 U.S. at 86–88.

Additionally, contrary to the Commissioner's urging, we find *Mulready* instructive. *First*, the Commissioner's argument that the Tenth Circuit was wrong to assume that pharmacy networks are a part of prescription-drug-benefit design fails because it relies on the physician-pharmacist distinction dismissed above. *Second*, his insistence that the case relied too heavily on *Nichols* also gets him nowhere considering our earlier discussion of that case. And as to the former, we note that the Commissioner premises his entire preemption argument on a single prong of the connection-with analysis—whether the PBM laws require a plan to "provide

specific substantive benefits." (Appellant Br., ECF 19, 34 (citation modified)). But he ignores the other three ways that a state law may be connected with ERISA: where the law (1) mandates or prohibits certain benefit plan structures, (2) "governs a central matter of plan administration," or (3) "interferes with nationally uniform plan administration." *See Rutledge*, 592 U.S. at 86–87; *Shaw*, 463 U.S. at 97. And laws forcing a plan to include pharmacies it may not otherwise include, like the AWP provisions, exercise control over a matter central to the administration of benefit plans—the design and structure of the plans. That is impermissible under ERISA. *Rutledge*, 592 U.S. at 86–87.

Finally, we are not persuaded to treat the PBM laws as cost regulations like those approved in *Rutledge*. The Arkansas law at issue in *Rutledge* had "three key enforcement mechanisms": (1) requiring PBMs to "tether reimbursement rates to pharmacies' [drug] acquisition costs," (2) mandating that PBMs establish "administrative appeal procedures for pharmacies to challenge" those reimbursement prices, and (3) allowing pharmacies to "decline to sell a drug to a beneficiary" should the PBM "reimburse the pharmacy at less than its acquisition cost." 592 U.S. at 84–85. These requirements were a mere "form of cost regulation," the effect of which was not "so acute" that it "effectively dictate[d] plan choices," and thus did "not have an impermissible connection with an ERISA plan." *Id.* at 88.

But Tennessee's AWP provisions differ from the Arkansas law in *Rutledge* because they go beyond regulating PBM reimbursement rates as cost regulations. The AWP provisions diminish, if not outright eliminate, a plan's ability to design its network in a way most accommodating and beneficial to its participants. *See Mulready*, 78 F.4th at 1198 (explaining that the pharmacies included in a network is a "key benefit design[] for an ERISA plan"). So we reject the comparison. Tennessee's AWP laws have an impermissible connection with ERISA and are preempted.

2. Incentive Provisions

The incentive provisions include provisions that both incentivize and disincentivize certain conduct and are found in Tenn. Code Ann. §§ 56-7-3120(a), (b)(2), and 3121(c). Section 3120(a) bars PBMs and covered entities from requiring plan participants to "pay an additional

fee, higher copay, higher coinsurance, second copay, second coinsurance, or other penalty when obtaining prescription drugs, including specialty drugs from a contracted pharmacy." Tenn. Code Ann. § 56-7-3120(a). Section 3120(b)(2) prohibits PBMs or covered entities from "[o]ffer[ing] financial or other incentives" to participants "to persuade the[m] . . . to utilize a pharmacy owned by or financially beneficial to the [PBM] or covered entity." *Id.* at § 56-7-3120(b)(2). And § 3121(c) prohibits PBMs from charging a plan participant "a different copayment obligation or additional fee, or provide any inducement or financial incentive, for using any pharmacy" in a pharmacy network established by a PBM to serve participants in Tennessee. *Id.* at § 56-7-3121(c).

The incentive provisions impede cost-sharing arrangements, an important facet of pharmacy network structure. These arrangements divvy up the allocation of who bears what cost and include things like copays and coinsurance. The D.C. Circuit has concluded that a PBM-focused law precluding adoption of a cost-sharing arrangement may "function as a regulation of an ERISA plan itself." *PCMA v. Dist. of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010) (citation omitted). Here, the PBM laws regulate ERISA plans directly, as such plans are included in the definition of both "covered entity" and "pharmacy benefits manager." Tenn. Code Ann. § 56-7-3102(1)(A)(xii), (5); *see also id.* at § 56-7-3122 ("Notwithstanding another law, this part applies to plans governed by [ERISA]."). Regardless, the incentive provisions bar ERISA plans operating in Tennessee from steering plan participants toward or away from certain pharmacies with higher or lower cost-sharing arrangements. This restriction operates to require an ERISA plan to "structure [its] benefit plans in [a] particular way[]." *Rutledge*, 592 U.S. at 86–87.

And the incentive provisions are more than mere cost regulations like the Court approved in *Rutledge*. 592 U.S. at 88. The effect of Tennessee's incentive provisions is to impose across-the-board, universal copays and other fees at every pharmacy in a given network. *See Mulready*, 78 F.4th at 1198 (concluding that the discount prohibition at issue there "require[d] that cost-sharing and copayments be the same for all network pharmacies."). As the district court observed, "forbidding differential cost-sharing structures is the same as requiring identical cost-sharing structures." (Op. & Ord., R. 142, PageID 2221 (citing *Mulready*, 78 F.4th

at 1198)). Thus, it goes beyond "merely increas[ing] costs or alter[ing] incentives for ERISA plans." *Rutledge*, 592 U.S. at 88. It is an impermissible dictate seeking to control how a plan is designed and structured. *See Mulready*, 78 F.4th at 1198 (explaining that the "cost-sharing arrangement[]" for in-network pharmacies is a "key benefit design[] for an ERISA plan."). So the effect of the incentive provisions is "so acute" that they "effectively dictate plan choices." *Rutledge*, 592 U.S. at 88. These provisions disrupt uniformity in McKee's Health Plan and impermissibly dictate its plan's design. We therefore conclude that ERISA preempts the incentive provisions, too.

B. Saving and Deemer Clauses

Our analysis does not stop at preemption, because even when a state's statute has an impermissible connection with ERISA plans, Congress included carveouts that could keep these laws in effect. The Commissioner argues that ERISA's saving clause applies to the Tennessee laws at issue. But this argument fails. To begin, neither the Commissioner nor the district court addressed it below. So, the argument is forfeited. *See Frenchko*, 160 F.4th at 803 ("Ordinarily, we will not address an issue not passed upon by the district court.") (citation modified).

Forfeiture aside, the Commissioner's saving clause argument is not persuasive. ERISA's saving clause exempts an otherwise preempted state law if it "regulates insurance." 29 U.S.C. § 1144(b)(2)(A). But there is also the "deemer clause," which says, in relevant part, that "an employee benefit plan . . . shall [not] be deemed to be an insurance company or other insurer, . . . or to be engaged in the business of insurance . . . for purposes of any law of any State purporting to regulate insurance companies[] [or] insurance contracts." *Id.* at § 1144(b)(2)(B). These two provisions, plus ERISA's preemption provision, operate as follows: (1) "If a state law relates to employee benefit plans, it is pre-empted"; (2) "The saving clause excepts from the pre-emption clause laws that regulate insurance"; and (3) "The deemer clause makes clear that a state law that purports to regulate insurance cannot deem an employee benefit plan to be an insurance company." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 45 (1987) (citation modified).

We need not decide whether the PBM laws regulate insurance, because even if they do, the deemer clause steps in and prevents the PBM laws from deeming McKee, its Plan, or its

PBM to be insurance companies. The deemer clause "exempt[s] self-funded ERISA plans from state laws that regulate insurance within the meaning of the saving clause." *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (citation modified). Under the PBM laws, ERISA plans are considered to be PBMs—a fact the Department acknowledged in a response to a public hearing comment—and self-funded ERISA plans *cannot* be treated as an insurance company under ERISA. *See* 29 U.S.C. § 1144(b)(2)(B); Tenn. Code Ann. § 56-7-3102(5).[4] Thus, the saving clause does not apply; Tennessee's PBM laws at issue in this case are preempted.

The Commissioner argues that there is "no material difference between a principal insurer and a PBM engaged in pharmacy networking," and that PBMs have therefore "invited regulation as insurers under state law" so as to trigger the saving clause. (Appellant Br., ECF 19, 44, 47 (citation modified)). But because Tennessee included ERISA plans in the definition of a PBM, the PBM laws' regulation of PBMs captures those ERISA plans within it. Accordingly, even if the saving clause applies here, the deemer clause jumps in to allow preemption.

And because we conclude that ERISA's express preemption provision applies, we need not address the alternative argument regarding implied preemption. *See In re Ford Motor Co. F-150 & Ranger Truck Fuel Econ. Mktg. & Sales Pracs. Litig.*, 65 F.4th 851, 860 n.6 (6th Cir. 2023) (declining to address express preemption argument where implied preemption resolved the case).

V.

States can enact laws looking to regulate health care and PBMs. But those laws cannot trespass into ERISA's territory. Because the Tennessee laws McKee challenges have an impermissible connection with ERISA plans, they are preempted.

We AFFIRM.

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[4]To avoid any confusion that the Department's response refers to a self-insured plan governed by ERISA (which *would be* "bound by state insurance regulations insofar as they apply to the plan's insurer," *Holliday*, 498 U.S. at 61), the statutory definitions of "covered entity" and "pharmacy benefits manager" separate out "self-insured entity" or "self-insured entities" and "plans governed by" ERISA. *See* Tenn. Code Ann. § 56-7-3102(1)(A)(xi)–(xii), (5).