No. 18-2926

In the

United States Court of Appeals

for the

Eighth Circuit

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff-Appellant,

v.

DIRK WILKE,* et al.,

Defendants-Appellees.

On appeal from the United States District Court
for the District of North Dakota
Case No. 17-cv-141 - Hon. Daniel J. Hovland

REPLACEMENT OPENING BRIEF OF APPELLANT PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

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* By operation of Federal Rule of Civil Procedure 25(d), Dirk Wilke, in his official capacity as the Interim State Health Officer of North Dakota, is automatically substituted for the prior named defendant, Mylynn Tufte.

SUMMARY OF THE CASE

This appeal presents the question whether two North Dakota statutes, N.D. Cent. Code §§19-02.1-16.1 and 19-02.1-16.2, are preempted by the express preemption clauses of the Employee Retirement Income Security Act of 1974 (ERISA) and the Medicare statute. Sections 16.1 and 16.2 regulate how ERISA and Medicare Part D plan sponsors, through their pharmacy benefit managers (PBMs), design and provide prescription drug benefits to plan members in North Dakota.

In prior proceedings in this case, the Court held that Sections 16.1 and 16.2 are preempted by ERISA but declined to reach the question of Medicare preemption. *See PCMA v. Tufte*, 968 F.3d 901 (8th Cir. 2020). The Supreme Court subsequently reversed this Court's decision in *Rutledge v. PCMA*, 141 S. Ct. 474 (2020), which concerned ERISA preemption of a separate and distinct Arkansas law. It then granted North Dakota's petition for a writ of certiorari in this case, vacated this Court's original judgment (which had expressly rested on *Rutledge*), and remanded for further proceedings. This Court ordered the parties to re-brief the merits in light of *Rutledge*.

Given the multifaceted nature of the statutes at issue here, the practical importance of the questions presented, and recent developments in preemption law, appellant Pharmaceutical Care Management Association (PCMA) respectfully submits that oral argument would assist the Court with its resolution of this appeal. PCMA requests 30 minutes per side.

CORPORATE DISCLOSURE STATEMENT

The Pharmaceutical Care Management Association is a nonprofit Section 501(c)(6) membership association. It has no parent corporation, and no publicly held corporation owns 10 percent or more of its stock.

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INTRODUCTION

This appeal presents the question whether two North Dakota statutes, North Dakota Century Code §19-02.1-16.1 (Section 16.1) and §19-02.1-16.2 (Section 16.2), are preempted as applied to pharmacy benefit managers (PBMs) furnishing services to prescription drug benefit plans covered by ERISA or offered under the Medicare Part D program. The district court held that they are not. But in prior appellate proceedings, this Court disagreed. Relying principally on its decision in *PCMA v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018), it held that Sections 16.1 and 16.2 are preempted entirely by ERISA because they have an "implicit reference to ERISA plans[,] result[ing] in preemption." *PCMA v. Tufte*, 968 F.3d 901, 905 (8th Cir. 2020). Having so held, the Court declined to reach the Medicare preemption question. *Id*. at 907 n.3.

In the meantime, the Supreme Court granted review and reversed in *Rutledge*. *See* 141 S. Ct. 474 (2020). As relevant here, the Supreme Court abrogated this Court's "'implicit reference' to" standard for ERISA preemption. *Id*. at 479. The question now presented is whether Sections 16.1 and 16.2 are preempted under alternative theories of ERISA preemption and separately under Medicare Part D. Unquestionably, they are.

The Supreme Court's cases teach that ERISA preempts state laws (1) "dealing with the subject matters covered by ERISA—reporting, disclosure, fiduciary responsibility, and the like" (*Shaw v. Delta Air Lines, Inc.*, 463

U.S. 85, 98 (1983)) and (2) requiring plans to adopt a "particular scheme of substantive coverage" (*Rutledge*, 141 S. Ct. at 480). Such laws, the Supreme Court has said, have an impermissible "connection with" ERISA plans, bringing them within its preemptive scope. That describes all the essential elements of Sections 16.1 and 16.2. If ERISA's preemption clause means anything, moreover, it means that federal standards occupy the field of laws relating to benefit plans covered by ERISA. Sections 16.1 and 16.2 are alternatively preempted on that basis as well.

The same goes for Medicare preemption. As the First Circuit has explained, "Congress's purpose in enacting § 1395w-26(b)(3) was" to ensure that Medicare remains "a federal program operated under Federal rules" and that "[s]tate laws, do not, and should not apply." *First Med. Health Plan, Inc. v. Vega-Ramos*, 479 F.3d 46, 51-52 (1st Cir. 2007). Thus, Sections 16.1 and 16.2 are preempted as applied to Medicare plans. That is alternatively so because there is a good textual indication that Congress intended the same test to apply to Medicare preemption as applies to ERISA preemption. Regardless of which analytical approach the Court takes, the conclusion remains: Sections 16.1 and 16.2 are preempted in their entireties as applied to plans covered by ERISA and offered under Medicare Part D.

JURISDICTION

The district court's jurisdiction rested on 28 U.S.C. §1331. The district court entered an amended judgment on October 17, 2018, and PCMA filed a

timely notice of appeal the same day. This Court's jurisdiction is invoked under 28 U.S.C. §1291. On August 7, 2020, this Court entered judgment in favor of PCMA and issued its mandate on September 9, 2020. Defendants filed a timely petition for a writ of certiorari, which the Supreme Court granted on February 22, 2021. On March 26, 2021, the Supreme Court entered its judgment, vacating this Court's prior judgment and returning jurisdiction to this Court.

STATEMENT OF ISSUES

The first issue presented is whether ERISA's express preemption clause, 29 U.S.C. §1144(a), preempts Sections 16.1 and 16.2 as applied to ERISA-covered prescription drug plans. The most apposite cases are *Rutledge v. PCMA*, 141 S. Ct. 474 (2020); *Gobeille v. Liberty Mutual Insurance Co.*, 577 U.S. 312 (2016); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983); and *Kentucky Association of Health Plans v. Miller*, 538 U.S. 329 (2003). The pertinent statutes are 29 U.S.C. §1144(a) and Sections 16.1 and 16.2.

The second issue presented is whether Medicare Part D's express preemption clause, 42 U.S.C. §1395w-112(g), preempts Sections 16.1 and 16.2 as applied to Medicare Part D prescription drug plans. The most apposite cases are *PCMA v. Rutledge*, 891 F.3d 1109 (8th Cir. 2018); *First Medical Health Plan, Inc. v. Vega-Ramos*, 479 F.3d 46 (1st Cir. 2007); *Uhm v. Humana*, 620 F.3d 1134 (9th Cir. 2010); and *Morales v. Trans World Airlines*, 504 U.S. 374

(1992). The pertinent statutes are 42 U.S.C. §§ 1395w-26(b)(3) and 1395w-112(g) and Sections 16.1 and 16.2.

STATEMENT OF THE CASE

A. Legal background

1. ERISA preemption

a. To encourage employers to offer benefits, ERISA aims to establish a "uniform regulatory regime over employee benefit plans." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004). Essential to achieving that objective is ERISA's "comprehensive" preemption clause. *Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312, 319 (2016). "[B]y mandating certain oversight systems and other standard procedures" pursuant to uniform federal rules, ERISA "make[s] the benefits promised by an employer more secure" for employees while at the same time reducing the administrative burdens for multistate employers, who otherwise would face state-by-state variation in regulations. *Id*. at 320-321. ERISA's preemption clause "minimiz[es] the administrative and financial burden[s] on plan administrators—burdens ultimately borne by the beneficiaries" by prohibiting States from "[r]equiring ERISA administrators to master the [50 states'] relevant laws." *Id.* at 321.

To that end, Congress has specified that ERISA's "provisions … shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by the statute. 29 U.S.C. §1144(a). With this language, Congress "intended to preempt the field for Federal

regulations, thus eliminating the threat of conflicting or inconsistent State and local regulation of employee benefit plans." *Shaw*, 463 U.S. at 99 (quoting 120 Cong. Rec. 29,933 (Aug. 22, 1974)). That is, Congress sought to ensure that "employee benefit plan regulation would be 'exclusively a federal concern.'" *Davila*, 542 U.S. at 208.

b. Consistent with the general observation, the Supreme Court has construed the words "relate to" in Section 1144(a) to mean state laws that have either a "connection with" or a "reference to" ERISA plans. *Gobeille*, 577 U.S. at 319-320. Only "connection with" preemption is relevant here.

State laws have a "connection with" ERISA plans in three scenarios. ***First***, a state law will have an impermissible connection with ERISA plans if it "bind[s] plan administrators to [a] particular choice" concerning the substance of plan benefits or the scope or identities of plan beneficiaries. *Rutledge*, 141 S. Ct. at 480. Regulations of this sort "prohibit[] employers from structuring their employee benefit plans in a [particular] manner" and are preempted. *Shaw*, 463 U.S. at 97. They stand in contrast to mere "rate regulation[s]," which have only "an indirect economic effect on choices made by insurance buyers, including ERISA plans" but do not "bind plan administrators to any particular choice" concerning plan design. *N.Y. State Conf. of BCBS Plans v. Travelers Ins. Co.*, 514 U.S. 645, 659, 667 (1995).

Second, "state laws dealing with the subject matters covered by ERISA" also have a connection with ERISA plans and are preempted. *Shaw*,

463 U.S. at 98; *Rutledge*, 141 S. Ct. at 482 n.2 (distinguishing laws that "overlap with 'fundamental components of ERISA regulation'"). In *Gobeille*, for example, the Court explained that "ERISA's reporting, disclosure, and recordkeeping requirements for welfare benefit plans are extensive." 577 U.S. at 321. The Court thus concluded that a state law that "compels [the disclosure of] detailed information" by third-party administrators to state authorities was preempted. *Id*. at 323. "[T]he uniform rule design of ERISA makes it clear that these decisions are for federal authorities, not for the separate States." *Id*. at 323-324.

Third, state laws that "'govern[] a central matter of plan administration' or 'interfere[] with nationally uniform plan administration'" have a connection with ERISA plans and are preempted. *Gobeille*, 577 U.S. at 320 (quoting *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 148 (2001)). "Plan administration includes 'determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements.'" *PCMA v. District of Columbia*, 613 F.3d 179, 185 (D.C. Cir. 2010).

2. Medicare Part D and Medicare preemption

Medicare is the federally-funded health insurance program for people who are 65 years or older and certain younger people with certain disabilities or with end-stage renal disease. It consists of four parts: Parts A, B, C, and D.

See Medicare Program; Establishment of the Medicare Advantage Program, 70 Fed. Reg. 4,588, 4,588 (Jan. 28, 2005).

Part D is Medicare's offering for outpatient prescription drug benefits. It authorizes private companies to contract with the Centers for Medicare and Medicaid Services (CMS) to provide partially-subsidized prescription drug coverage. The Part D program was created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Before enactment of the MMA, Medicare's express preemption provision specified a conflict-preemption standard, requiring the invalidation only of state standards that were "inconsistent with [federal] standards." 42 U.S.C. §1395w-26(b)(3)(A) (2002). The MMA expanded this provision; now, all State laws and standards regulating "with respect to [Medicare] plans" are preempted. 42 U.S.C. §1395w-26(b)(3). *See also* 42 U.S.C. §1395w-112(g) (incorporating Section 1395w-26(b)(3) into the Part D program).

"Congress's purpose in enacting § 1395w-26(b)(3) was to protect the purely federal nature of … plans operating under Medicare." *First Med.*, 479 F.3d at 52. Medicare's preemption clause thus ensures that the Part D prescription drug program remains "a federal program operated under Federal rules" and that "[s]tate laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency." *Id*. at 51 (quoting H. Conf. Rep. 108-391, at 557). There is no question that, in light of the 2003 changes to the clause, "Congress intended to broaden the pre-

emptive effects of the Medicare statutory regime" beyond mere conflict preemption. *Uhm v. Humana, Inc.*, 620 F.3d 1134, 1149 (9th Cir. 2010).

B. Factual background

1. Prescription benefit plans and PBMs

a. The great majority of healthcare benefit plans, including those covered by ERISA and Medicare, include coverage for prescription drugs.

A prescription drug benefit is a contractual entitlement to receive reimbursement for the purchase of specified drugs under the terms provided in the plan documents. The design of a prescription drug benefit is multifaceted. Plan sponsors must choose what drugs to cover; what level of patient cost-sharing to offer; what cost-control measures to implement; and what kind of pharmacy network to use. App.58-59, 69-70, 74, 82-83.

The complex interrelationships among drug manufacturers, wholesalers, and pharmacies make the negotiation and structuring of pharmacy benefits exceedingly complicated. Plan sponsors—that is, employers who establish, maintain and terminate plans—therefore typically hire pharmacy benefit managers (PBMs) to manage prescription-drug benefits at their direction. In fact, over 90% of Americans with coverage receive their prescription-drug insurance benefits through a PBM. *See* Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale L. & Pol'y Rev. 360, 364 (2020). PBMs work at the direction of plan sponsors to design and administer

prescription drug benefits. Unlike plan sponsors, PBMs do not exercise independent discretion and are not fiduciaries. App.58-59, 69-70, 82-83; *D.C.*, 613 F.3d at 183-185.

b. Plans generally require plan participants to obtain drugs from a predefined network of pharmacies. App.59. Variation in provider networks is one of the most important distinguishing features among competing benefit plans, and plan sponsors can (and typically do) offer a range of different network options. Some plans offer broad pharmacy networks in exchange for higher premiums. *See* CMS, *What You Should Know about Provider Networks*, perma.cc/TZ9Q-9ZCM. Other plans use significantly narrower networks through which they can achieve deeper discounts, offering participants a more limited benefit at lower cost. *Id*. Sponsors also will sometimes designate preferred providers, who give deeper discounts and where participants accordingly will pay smaller co-pays. *Id.*; *see also Sw. Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 439 (5th Cir. 2013). They also sometimes require participants to obtain certain drugs from specialty pharmacies, many of which are mail-service only. App.65, 78.

In constructing a network, PBMs typically require pharmacies to meet various credentialing standards beyond those required by state licensing laws, including those for billing systems, liability insurance, inventory capacities, regulatory compliance histories, and employee training. App.59-60, 63-64, 76-77, 85-86. They also often design their networks to incorporate perfor-

mance standards that hold network members accountable for such requirements as promoting generic alternatives, dispensing efficiently, and ensuring that patients actually take the medications dispensed. App.61, 72-73.

PBMs or plan sponsors also typically set separate credentialing standards for specialty pharmacies that manage drug regimens for patients with especially complex medical conditions requiring special storage, inventory control, and shipping. App.63, 75-76, 87. They also often limit which pharmacies may mail or deliver drugs consistent with the terms for reimbursement. This is principally for patient safety reasons, as not all pharmacies satisfy licensing, accreditation, and safety requirements for mailing or delivering drugs. App.64, 87-88.

2. Sections 16.1 and 16.2

Certain elements of Sections 16.1 and 16.2 regulate the design of prescription drug benefits, PBM and plan disclosures, and conflicts of interest. For example, Sections 16.1 and 16.2 dictate various aspects of a plan's provider network and benefit coverage design:

§ 16.1(11) & § 16.2(4).....	Prohibit PBMs from requiring pharmacies, as part of network design, to satisfy accreditation or recertification standards that exceed federal and state regulatory requirements.
§ 16.1(3).....	Limits PBMs' ability to impose performance standards and performance fees on network pharmacies.
§ 16.2(5).....	Appears to authorize a pharmacy to "dispense any and all drugs allowed under [its] license" as a covered drug, notwithstanding a plan's express limitation on covered

drugs (its formulary) or its requirements for preauthorization or step therapy, which apply to drugs that are especially costly or more likely to be abused.

§ 16.1(8)..... Authorizes network pharmacies—notwithstanding any contrary network design provisions in plan documents—to "mail or deliver drugs to a patient as an ancillary service of a pharmacy."

§ 16.1(9)..... Forbids a PBM from "prohibit[ing] a pharmacist or pharmacy from charging a shipping and handling fee," which is a cost borne directly by the participant.

Other provisions regulate plan and PBM disclosures:

§ 16.2(2)..... Requires that, upon request, PBMs with an ownership interest in a pharmacy disclose to plan sponsors the difference between the amount paid to such a pharmacy and the amount charged to a plan sponsor.

§ 16.1(10)..... Requires plans and PBMs, upon request, to provide pharmacies "with the processor control number, bank identification number, and group number for each pharmacy network established or administered by a pharmacy benefits manager."

§ 16.1(5)..... Allows pharmacies to "disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement paid to the pharmacy," notwithstanding contrary plan terms.

§ 16.1(7)..... Bars plans through their PBMs from restricting the information that pharmacies may provide to patients. It authorizes pharmacies to provide "relevant information to a patient," including plan reimbursement information.

§ 16.1(9)..... Forbids a PBM from "prohibit[ing] a pharmacist or pharmacy from charging a shipping or handling fee," which is a cost borne directly by the participant.

Still another section, in addition to Section 16.2(2), regulates perceived conflicts of interest and transactions with interested parties:

§ 16.2(3)..... Forbids PBMs from having an "ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the [PBM] agrees to not participate in a transaction that benefits the [PBM] instead of another person owed a fiduciary duty."

Finally, only two challenged sections arguably regulate pharmacy costs and reimbursement:

§ 16.1(2)..... Regulates fees that PBMs can charge pharmacies in connection with claim processing and adjudication

§ 16.1(4)..... Regulates reimbursements by allowing pharmacies to retain adjudicated costs when a member pays a copay.

C. Procedural background

1. PCMA filed a complaint challenging Sections 16.1 and 16.2 as preempted by ERISA and Medicare Part D, as applied to plans covered respectively by those statutes. App.17-22.

The district court granted in part and denied in part each side's motion for summary judgment. *First*, the district court held that ERISA does not preempt the challenged provisions of Sections 16.1 and 16.2. It reasoned that Sections 16.1 and 16.2 do not have any "connection with" ERISA plans. Add.14-17. According to the district court, Sections 16.1 and 16.2 do not "impose any requirements on ERISA plans" themselves and instead "largely

regulate[] pharmacy services, certain fees, and communication between pharmacies, their customers, and PBMs." Add.16-17.

Second, the district court held that Medicare Part D did not preempt the challenged provisions, save for one provision, Section 16.2(2), which the district court agreed overlapped with a Medicare regulation. Add.17-34. The Court entered judgment accordingly. Add.35-37.

2. This Court reversed the district court's rejection of PCMA's ERISA preemption claims. *See PCMA v. Tufte*, 968 F.3d 901 (8th Cir. 2020). Relying on its prior decisions in *Rutledge* and *PCMA v. Gerhart*, 852 F.3d 722 (8th Cir. 2017), the Court held that Sections 16.1 and 16.2 have an impermissible "reference to" ERISA plans. *See* 968 F.3d at 905 (explaining that the laws at issue in *Rutledge* and *Gerhart* "implicitly referred to ERISA" and, "[a]s in *Gerhart* and *Rutledge*, so too here"). The Court did not address PCMA's contention that Sections 16.1 and 16.2 are preempted under "connection with" preemption. *Id.*

The Court further concluded that ERISA preempts Sections 16.1 and 16.2 "in [their] entirety." 968 F.3d at 907 n.3. Having so held, it did not address PCMA's argument that Sections 16.1 and 16.2 are preempted as applied to Part D plans. *Id*.

3. After this Court decided the first appeal in this case, the Supreme Court issued its decision in *Rutledge*, which concerned Arkansas's regulation of maximum allowable cost (MAC) lists for generic drug reimbursements to

pharmacies. The law at issue in *Rutledge* requires PBMs to update their MAC lists within a fixed period following an increase in pharmacy acquisition costs. Ark. Code Ann. §17-92-507(c)(2). It provides further that PBMs must share their MAC lists with pharmacies and notify them of updates. *Id*. §17-92-507(c)(1), (3). PBMs must also "[p]rovide a reasonable administrative appeal procedure" that allows pharmacies to challenge MAC-based reimbursements. *Id*. §17-92-507(c)(4)(A)(i)(b). As the district court below noted, this Arkansas law is substantively distinct from Sections 16.1 and 16.2, which do "not mandate any specific practice regarding MAC methodology or [pharmacy] reimbursement rates." Add.15.

In holding that ERISA does not preempt the Arkansas MAC-list regulation, the Supreme Court described it as "a form of cost regulation." *Rutledge*, 141 S. Ct. at 481. Such laws do not "bind plan administrators to any particular choice" concerning the design of prescription drug coverage. *Id*. at 480; *see also id*. ("ERISA does not pre-empt" state laws "that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage"). The Supreme Court held further that the Arkansas law did not have an impermissible "reference to" ERISA plans. *Id*. at 483.

Following its decision in *Rutledge*, the Supreme Court granted North Dakota's petition for a writ of certiorari, vacated, and remanded for this

Court's consideration anew of PCMA's preemption arguments. *See Wilke v. PCMA*, 141 S. Ct. 1364 (2021).

SUMMARY OF ARGUMENT

I. The district court, in rejecting PCMA's preemption claims, applied a presumption against preemption. The Supreme Court has recently clarified that there is no such presumption in the context of express preemption clauses. In resolving this appeal, the Court therefore must consider the meaning of the statutory text alone, without a presumption against preemption.

II. *Rutledge* confirms only that Sections 16.1 and 16.2 lack an impermissible "reference to" ERISA plans. Beyond that, *Rutledge* sheds little light on the North Dakota statutes challenged here. The Arkansas MAC-list law at issue in *Rutledge* was held not preempted because it constituted a mere rate regulation, setting a floor for reimbursement rates for generic drugs. Sections 16.1 and 16.2 are not such laws; rather, they directly regulate benefit design and substantive subject matters covered by ERISA. Thus, whereas Arkansas's MAC-list law was not preempted, the opposite is true of North Dakota's Sections 16.1 and 16.2.

III. A. In particular, Sections 16.1 and 16.2 have an impermissible "connection with" ERISA plans. Significant elements of Sections 16.1 and 16.2 regulate the terms for the design of a plan's provider network and other elements of coverage. The scope of a plan's network and the conditions for

reimbursement are integral to the benefit itself. By limiting the choices that plan sponsors may make in designing plan benefits, Sections 16.1 and 16.2 have an impermissible "connection with" ERISA plans.

Other major elements of Sections 16.1 and 16.2 concern subject matters already covered by ERISA itself. In particular, ERISA and its implementing regulations include detailed disclosure and reporting requirements and govern conflicts of interest and interested-party transactions. By purporting to regulate in these same areas, Sections 16.1 and 16.2 necessarily have an impermissible connection with ERISA plans.

It does not change matters that Sections 16.1 and 16.2 apply most immediately to PBMs rather than plan sponsors themselves. The laws at issue here regulate the choices that plan sponsors make concerning plan design; require disclosure of a plan's information; and regulate the terms of the relationships that plans may have with PBMs. A state can no more interfere in these matters when the relevant tasks are carried out by a PBM at the plan's direction than it can if the plan assumes those roles for itself.

B. The Court can alternatively hold that Sections 16.1 and 16.2 are preempted because ERISA occupies the field of laws that "relate to" covered benefit plans. Here, ERISA occupies the field, in particular, of regulations concerning benefit design, disclosures and recordkeeping, and conflicts of interest and interested-party transactions. North Dakota's efforts, with Sections 16.1 and 16.2, to supplement federal standards in these areas plainly

"relate to" ERISA-covered plans within the meaning of Section 1144(a) and are therefore preempted.

III. A. For many of the same reasons, Sections 16.1 and 16.2 are preempted as applied to Part D plans. Courts have uniformly recognized that, in enacting Sections 1395w-26(b)(3) and 1395w-112(g), Congress intended to subject the Medicare Part D program to exclusive federal regulation. With limited exceptions, therefore, state regulation "with respect to" Part D plans is preempted. 42 U.S.C. §§ 1395w-26(b)(3), 1395w-112(g). At minimum, field preemption principles apply to Medicare preemption, and any overlap with federal standards is forbidden.

Sections 16.1 and 16.2 purport to supplement Medicare's exclusively federal scheme and thus fail this test. Federal statutory and regulatory standards specify that regulators must not "interfere" with a plan's negotiation of terms with network-participating providers. Congress set basic "reasonableness" guardrails for network terms, but otherwise intended for market forces to determine the best balance between access and affordability, ensuring that consumers would have a robust range of options to meet their needs. Sections 16.1 and 16.2 intrude in this area of regulation by dictating a litany of terms for the relationships between plans and network providers. That conclusion finds additional and unassailable support from the extraordinarily detailed scheme of federal standards that overlap in every relevant respect with Sections 16.1 and 16.2.

B. Alternatively, Sections 16.1 and 16.2 have an impermissible "connection with" Part D plans. The Supreme Court's cases hold that when Congress uses language similar to ERISA's preemption clause, as it did for Medicare, courts may use the same analytical approach to the preemption question as they do under ERISA. For all the reasons that Sections 16.1 and 16.2 have an impermissible "connection with" ERISA-covered plans, they have such a connection with Part D plans.

C. The district court held alternatively that Sections 16.1 and 16.2 are saved from preemption by other statutory provisions. Not so. One of the clauses the court invoked, Section 1395, is not a saving clause at all. Even if it were, it would not apply because neither plans nor their PBMs limit the ways in which physicians practice medicine. The other clause is equally inapplicable because neither Section 16.1 nor 16.2 is a "licensing law." Sections 16.1 and 16.2 are thus not saved from preemption.

STANDARD OF REVIEW

This Court reviews de novo the district court's resolution of cross-motions for summary judgment. *Lexicon, Inc. v. ACE Am. Ins. Co.*, 634 F.3d 423, 425 (8th Cir. 2011).

ARGUMENT

The Supreme Court's reversal in *Rutledge* makes clear that Sections 16.1 and 16.2 are preempted not under "reference to" preemption, as the Court originally held, but instead under ERISA "connection with" preemp-

tion—or alternatively under traditional field preemption principles. *Rutledge* also left this Court's Medicare preemption framework (modeling a field preemption analysis) intact. Considering these doctrines, the result called for now is effectively the same as before: The Court can and should invalidate the challenged provisions as applied to benefit plans covered by ERISA or offered under the Medicare Part D program.[1]

I. THERE IS NO PRESUMPTION AGAINST PREEMPTION IN THE CONTEXT OF EXPRESS PREEMPTION CLAUSES

The district court below applied a presumption against preemption, opining that "[c]ourts must start their inquiry with the assumption" that preemption does not apply. Add.6. That is incorrect.

In *Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938 (2016), the Supreme Court held that, when a statute "contains an express pre-emption clause, [courts] do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *Id*. at 1946. Although *Franklin* involved a bankruptcy statute, the Court cited *Gobeille* as an example of a case in which the presumption was held inapplicable. *Id*.; *see also Gobeille*, 577 U.S. at 325-326 (the "presumption against

[1] The Court previously held Sections 16.1 and 16.2 are preempted facially, as applied to *all* plans. We do not defend that result. Sections 16.1 and 16.2 should be preempted only as applied to ERISA-covered and Part D plans.

pre-emption, whatever its force in other instances, cannot validate a state law that enters a fundamental area of ERISA regulation").

The Fifth Circuit recently applied this reasoning in an ERISA case. *See Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan*, 938 F.3d 246, 258 (5th Cir. 2019). "Given that *Franklin* specifically references *Gobeille*—an ERISA case—when holding that there is no presumption [against] preemption when the statute contains an express preemption clause," the Fifth Circuit declined to apply the presumption to ERISA. *Id*. at 259. This Court should do the same.

II. *RUTLEDGE* CONFIRMS THAT SECTIONS 16.1 AND 16.2 REMAIN PREEMPTED

The threshold question for the Court is whether the Supreme Court's decision in *Rutledge* calls for a different result from the one originally reached by this Court. It does not.

Prior to the Supreme Court's decision in *Rutledge*, this Court had held that state laws regulating PBMs that "administer benefits for 'covered entities'" have an "implicit reference to ERISA" and are, for that reason, preempted. *Rutledge*, 891 F.3d at 1112 (quoting *Gerhart*, 852 F.3d at 729). The Court based its original decision in this case on that reasoning. *See* 968 F.3d at 905.

The Supreme Court subsequently rejected that reasoning in *Rutledge*, holding that Arkansas's MAC-list regulation "does not 'refer to' ERISA"

because it "does not act immediately and exclusively upon ERISA plans." 141 S. Ct. at 481. The Supreme Court's decision is thus relevant insofar as it abrogates the rationale on which this Court's prior decision was based.

Beyond that, however, *Rutledge*'s holding has limited relevance here. The Supreme Court held that Arkansas's MAC-list law was not preempted because it "amounts to nothing more than cost regulation," requiring PBMs "to reimburse pharmacies for prescription drugs at a rate equal to or higher than the pharmacy's acquisition cost." 141 S. Ct. at 481-482. But as the district court observed in earlier proceedings, that does not describe Sections 16.1 and 16.2, which do "not mandate any specific practice regarding MAC methodology or reimbursement rates." Add.15.

In explaining why Arkansas's MAC-list law is not preempted, moreover, the Supreme Court went to great lengths to explain why laws like North Dakota Sections 16.1 and 16.2 *are* preempted. It confirmed that ERISA preempts "laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits" and emphasized that the Arkansas law was not preempted because it did *not* "dictate plan choices" or "forc[e] plans to adopt any particular scheme of substantive coverage." 141 S. Ct. at 480-481. The Court also did nothing to disturb the longstanding rule that "state laws dealing with the subject matters covered by ERISA" are preempted, or more generally the concept that ERISA works a "preemption of the field." *Shaw*, 463 U.S. at 98-99; *accord Travelers*, 514 U.S. at 661.

Rutledge accordingly has little impact to the issues now presented for decision, except to confirm that the longstanding bases on which Sections 16.1 and 16.2 are preempted remain good law. To be sure, Sections 16.1 and 16.2 can no longer be said to have an "implicit reference to ERISA plans." 968 F.3d at 905. But neither can they be said to be "merely a form of cost regulation." 141 S. Ct. at 481. Quite apart from dictating price floors for reimbursement of generic drugs to pharmacies (Add.15), Sections 16.1 and 16.2 force plan sponsors to design prescription drug benefits in a particular manner and intrude on subject matters covered by ERISA. They are thus preempted, as we demonstrate below.

III. ERISA EXPRESSLY PREEMPTS SECTIONS 16.1 AND 16.2 AS APPLIED TO ERISA-COVERED PLANS

Sections 16.1 and 16.2 are preempted by ERISA in numerous respects, under both "connection with" preemption and, alternatively, traditional field preemption. Regardless what analytical approach the Court adopts, Sections 16.1 and 16.2 may not lawfully be applied to ERISA-covered benefit plans.

A. Sections 16.1 and 16.2 have an impermissible "connection with" ERISA plans

Sections 16.1 and 16.2 have a "connection with" ERISA plans within the meaning of the Supreme Court's cases. In particular, they bind plan sponsors to particular choices concerning benefit design and otherwise deal with the subject matters covered by ERISA.

1. Elements of Sections 16.1 and 16.2 impermissibly dictate benefit design

A state law has an impermissible connection with ERISA plans if it "bind[s] plan administrators to [a] particular choice" concerning the substance of plan benefits. *Rutledge*, 141 S. Ct. at 480; *accord Shaw*, 463 U.S. at 96-97 (laws "prohibit[ing] employers from structuring their employee benefit plans in a [particular] manner" are preempted). That describes many of the key elements of Section 16.1 and 16.2.

Network design (Sections 16.1(3), (8), (9), and (11) and 16.2(4)). The design of a plan's network of providers for covered health benefits is a substantive element of the benefit. Again, a prescription drug benefit is an entitlement to receive reimbursement for the purchase of covered drugs upon satisfaction of the terms of the plan. Needless to say, the nature and scope of the network of providers where covered drugs may be purchased for reimbursement is an essential element of the benefit.

The Supreme Court recognized as much in *Kentucky Association of Health Plans v. Miller*, 538 U.S. 329 (2003). That case concerned ERISA's Saving Clause (29 U.S.C. §1144(b)(2)(A)), which saves from preemption all generally applicable laws regulating insurance, as applied to fully-insured ERISA plans. *Miller*, 538 U.S. at 335-336. It involved, more specifically, a challenge to Kentucky's "any willing provider" law, which requires plans to admit into their provider networks any "provider who is willing and able to

meet its terms" for inclusion. *Id.* at 335. The Court held that the law was "saved from pre-emption" by the Saving Clause. *Id*. at 335-336. But a necessary predicate to that holding was the Supreme Court's conclusion that any-willing-provider laws regulate the design of plan benefits; otherwise, consideration of the Saving Clause would have been unnecessary.

The Fifth Circuit recognized as much in *CIGNA Healthplan of Louisiana v. Louisiana*, 82 F.3d 642, 648-649 (5th Cir. 1996). There, it held that requiring plans to adopt "a certain structure" for benefits, "i.e., a structure that includes every willing, licensed provider" within the plan's network, regulated benefit design. *Id*. at 648.

Several of the challenged provisions regulating the design of plans' provider networks are preempted on this ground. As described above (*supra*, at 10-12), Sections 16.1(3), (8), (9), and (11) and 16.2(4), and (5) all dictate choices concerning the design of provider networks: Sections 16.1(3), 16.1(11), and 16.2(4) prohibit PBMs from requiring, as a condition of network participation, that pharmacies satisfy accreditation or recertification standards that exceed federal and state regulatory requirements and curtail discretion to impose performance standards as a condition for participation in a network. But the pharmacies a plan sponsor includes in its network directly affect the benefits offered to plan members. *Where* a plan member can access covered drugs is an integral part of the benefit itself. *Miller*, 538 U.S. at 335-336; *CIGNA*, 82 F.3d at 648-649.

Sections 16.1(8) and 16.1(9) authorize network pharmacies—notwithstanding any limitation to the contrary in plan documents—to mail drugs and charge shipping and handling fees to participants. These provisions meet the same fate. The network pharmacies that a plan member may use for covered mail service is an element of the substantive benefit itself.

In sum, these various regulations of network design are preempted. *Rutledge*, 141 S. Ct. at 480.

Covered drugs and cost sharing (Sections 16.1(4), (8), and (9), and 16.2(5)). Section 16.2(5) states that a pharmacy must be allowed to "dispense any and all drugs allowed under [its] license." It is not entirely clear how this language should be read—whether it means that plans (or their PBMs) must allow pharmacies to dispense "any and all" drugs as *covered* drugs, or simply to dispense drugs, whether covered or not. If the latter reading is the correct one, then Section 16.2(5) accomplishes nothing. No plan sponsor or PBM forbids a pharmacy from dispensing drugs with a valid prescription; they only limit the circumstances in which dispensed drugs are covered.

If the former reading is correct—that plan sponsors cannot decline to cover a drug that a network pharmacy is licensed to dispense—then the provision is manifestly preempted. Use of formularies and limited lists of covered drugs is fundamental to the design of the benefit. It is self-evidently a matter of benefit design to require plans to cover all drugs that a pharmacist is licensed to dispense.

So too with respect to Sections 16.1(8) and (9), which specify that "[a] pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service" and may "charg[e] a shipping and handling fee to a patient requesting a prescription be mailed or delivered." If these provisions mean that plan sponsors and PBMs may not prohibit pharmacies from mailing drugs and charging for it, they accomplish nothing. No plan sponsor or PBM would purport to prevent pharmacies from delivering drugs by mail for a fee outside the context of the plan benefit. But if those provisions mean that plans must always *cover* any and all drugs delivered by mail and allow pharmacies to impose additional cost-sharing on patients, then they unquestionably are preempted. Again, the terms on which drugs are covered, and the level of participant cost-sharing, are integral to benefit design.

Cost-sharing—or the plan participant's financial responsibility at the point of sale—is a particularly critical element of benefit design. Cost sharing ordinarily takes the form of a copay or coinsurance. When a plan requires a copay, the copay amount is not necessarily tied to the cost of the drug itself. Plans instead use copays (unlike co-insurance) to spread the cost-sharing burden evenly across medicines that cost different amounts. But Section 16.1(4) places a cap on copays, specifying that they may not "exceed[] the cost of the medication." In that way, it purports to limit the range of choices that plan sponsors have in the design of the benefits they offer.

Each of these provisions "bind[s] plan administrators to [a] particular choice" concerning the substance and scope of plan benefits. *Rutledge*, 141 S. Ct. at 480. Each is therefore preempted.

2. Elements of Sections 16.1 and 16.2 impermissibly regulate subject matters covered by ERISA itself

In addition to laws regulating benefit design, "state laws dealing with the subject matters covered by ERISA" are preempted. *Shaw*, 463 U.S. at 98. Numerous elements of Sections 16.1 and 16.2 are preempted on this basis.

Disclosure standards (Sections 16.1(4), (5), (7), and (10), and 16.2(2)). "[R]eporting, disclosure, and recordkeeping are central to, and an essential part of, the uniform system of plan administration contemplated by ERISA." *Gobeille*, 577 U.S. at 323. According to this scheme, an ERISA plan must, among other things, "provide adequate notice in writing" of claims decisions and give a procedure for "full and fair review" of such decisions. 29 U.S.C. §1133. ERISA also requires every sponsor (or its third-party administrator acting on its behalf) to furnish a "summary plan description" that must be "sufficiently accurate and comprehensive" to give participants a meaningful understanding of the scope of benefits (29 U.S.C. §1022(a)) and include, among other things "the plan's requirements" for receiving benefits and "circumstances which may result in disqualification, ineligibility, or denial or loss of benefits" (*id*. §1022(b)). Federal regulations, in turn, elaborate in mind-spinning detail the information that must be covered, including

"provisions governing the use of network providers, the composition of the provider network, and whether, and under what circumstances, coverage is provided for out-of-network services." 29 C.F.R. §2520.102-3(j). *See also* IRS, et al., *Transparency in Coverage*, 85 Fed. Reg. 72,158 (Nov. 12, 2020) (final rule requiring group health plans to disclose cost-sharing information upon request, to participants).

Recent amendments to ERISA's regulation of group health plans additionally require substantial disclosures to federal authorities of data pertaining to pharmacy benefits and drug costs, in particular. *See* Consolidated Appropriations Act of 2021, div. BB, tit. II, §204(b), Pub. L. No. 116-260, *available at* perma.cc/3G23-NLZ3. Required annual disclosures include data concerning prescription drug spending; rebates, fees, and out-of-pocket costs; the number of enrollees; the number, nature, and size of claims; and so forth. *See id*. at PDF pp. 1738-1739.

Against this background, states are forbidden from supplementing federal standards concerning recordkeeping and disclosure requirements with respect to benefit plans. *Gobeille*, 577 U.S. at 323. Yet various provisions purport to do just that:

Section 16.1(4) prohibits PBMs from redacting certain information in paperwork shared with providers. As described above, ERISA already regulates the type and *to whom* information about plans must be disclosed.

Sections 16.1(5) and 16.1(7) prohibit limitations on the kind of information that may be disclosed to patients. As described above, ERISA already regulates what information about the plan must be disclosed to plan members. North Dakota law cannot require plans to permit additional disclosures of plan information to plan members.

Section 16.1(10) requires plans and PBMs, upon request, to provide network pharmacies with sensitive financial information about all the pharmacy networks they operate. As described above, ERISA already regulates what and to whom information about plans, like pharmacy networks they may use, must be disclosed.

Section 16.2(2) mandates disclosures by PBMs to plan sponsors of the differences between reimbursements and the rates billed by PBMs to plans for prescriptions filled by PBM-affiliated pharmacies. Again, as described above, ERISA already regulates what, how, and to whom information concerning plan finances must be disclosed.

These state-imposed disclosure rules explicitly overlap with subject matters covered by ERISA and are therefore preempted. *Shaw*, 463 U.S. at 98-99; *Travelers*, 514 U.S. at 661.

Conflict-of-interest standards (Sections 16.2(2) and (3)). ERISA also regulates transactions involving "part[ies] in interest" and potential conflicts of interest, including relationships with third-party administrators like PBMs. *See* 29 U.S.C. §1108(b). It specifies, in particular, that if a plan

"[c]ontract[s] or make[s] reasonable arrangements with a party in interest for … services necessary for the establishment or operation of the plan," the engagement is permissible "if no more than reasonable compensation is paid therefor." *Id*. The Department of Labor also has required third-party providers to make disclosures to prevent conflicts of interest. 29 C.F.R. §2550.408b-2(c) (service providers to ERISA-covered pension plans). DOL had considered as part of the same rulemaking to require "compensation and fee disclosures by PBMs," but declined. U.S. Dep't of Labor, *PBM Compensation and Fee Disclosure*, perma.cc/CDM8-HZW6. Congress also recently imposed additional disclosure requirements on "[b]rokerage" and "[c]onsulting" services for group health plans (Consolidated Appropriations Act of 2021, div. BB, tit. II, §202, Pub. L. No. 116-260), further confirming that plans' relationships with service providers is for exclusive federal control.

Section 16.2(3) regulates the same subject matter. It forbids PBMs from having an "ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the [PBM] agrees to not participate in a transaction that benefits the [PBM] instead of another person owed a fiduciary duty."

Similarly, Section 16.2(2) requires that, upon request, PBMs and third-party payers that have an ownership interest in a pharmacy disclose to plan sponsors the difference between the amount paid to a pharmacy and the amount charged to a plan sponsor. These provisions are intended to regulate

transactions with interested parties and thus fall within a subject matter expressly regulated by federal authorities under ERISA. They are therefore preempted. *Shaw*, 463 U.S. at 98.

3. It is of no moment that Sections 16.1 and 16.2 apply most immediately to PBMs rather than plan sponsors

It is no response to say, as the district court did (Add.17), that the laws here apply only to PBMs and "do[] not impose any requirements on ERISA plans" themselves. Neither ERISA nor Sections 16.1 and 16.2 draw any distinction between plans administering benefits on their own and plans that engage third parties to do so at their direction.

Nor would any such distinction make sense. Although Sections 16.1 and 16.2 apply most immediately to PBMs, they ultimately regulate the choices that plan sponsors are permitted to make concerning benefit design; require disclosure of a plan's information and data; and regulate the terms of the relationships that plans may have with PBMs. These are central matters of plan design and administration. A state can no more interfere with plan design and administration carried out by a plan's contractor at the plan's direction than it can if the plan assumes those roles for itself.

That was the D.C. Circuit's holding in *PCMA v. D.C.*, where it held that ERISA preempts regulations of "a PBM's administration of benefits on behalf of an" ERISA-covered benefit plan. 613 F.3d at 185. It also was the ground for the Supreme Court's decision in *Gobeille*. Although the Court expressly

recognized that Vermont's reporting requirement in that case fell directly on the plan's third-party administrator (577 U.S. at 317), the Court attached no significance to that observation. It held instead that the Vermont law "compel[led] *plans* to report" their information to state authorities and thus "intrud[ed] upon 'a central matter of plan administration.'" *Id.* at 323 (emphasis added). The Court did not even hint that it might make a difference that the reporting obligation was carried out as a practical matter by the ERISA plan's third-party administrator rather than the plan itself.

B. Alternatively, Sections 16.1 and 16.2 are field-preempted

a. The conclusion that Sections 16.1 and 16.2 are preempted under settled "connection with" principles is confirmed by the general rule that "the States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance." *Arizona v. United States*, 567 U.S. 387, 399 (2012). Under the field-preemption doctrine, if a state law "diminishes the Federal Government's control over enforcement or detracts from the integrated scheme of regulation created by Congress," it is preempted. *Arizona*, 567 U.S. at 402 (cleaned up) (quoting *Wisconsin Dep't of Industry v. Gould Inc.*, 475 U.S. 282, 288-289 (1986)). When field-preemption applies, in other words, it means that "Congress left no room for the States to supplement" federal standards, even with local rules that do not overlap entirely with federal rules. *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992).

These precedents independently require holding Sections 16.1 and 16.2 preempted. To be sure, the Supreme Court has not expressly grounded its ERISA preemption cases on the doctrine of field preemption. Yet early in ERISA's history, it acknowledged that the 93rd Congress, with ERISA, "intended to preempt the field for Federal regulations, thus eliminating the threat of conflicting or inconsistent State and local regulation of employee benefit plans." *Shaw*, 463 U.S. at 99 (quoting 120 Cong. Rec. 29,933 (Aug. 22, 1974)). In other words, Congress meant to "reserve[] to Federal authority the sole power to regulate the field of employee benefit plans." *Id.* (quoting 120 Cong. Rec. 29,197 (Aug. 22, 1974)). Thus both legislators and the Supreme Court understood early on that ERISA's express preemption clause works a "preemption of the field." *Id.* (quoting same).

Numerous justices of the Supreme Court have more recently endorsed this approach, reasoning that it is truer to the text of the statute to apply "ordinary field pre-emption" in ERISA cases. *Cal. Div. of Labor Standards Enf't v. Dillingham Constr.*, 519 U.S. 316, 336 (1997) (Scalia, J., concurring, joined by Ginsburg, J.).[2] These justices have noted that "recent ERISA cases" based on connection-with precedents are "consistent with [the] approach" of

[2] *See also Egelhoff*, 532 U.S. at 153 (Scalia, J., joined by Ginsburg, J.). At oral argument in *Rutledge*, Justice Alito expressed interest in adopting a field preemption approach to ERISA; counsel for the government agreed that doing so "would work," describing it as "a more text-based approach to ERISA preemption." *See* Oral Arg. Tr. 28-29, perma.cc/AC87-RS4Q.

"apply[ing] normal conflict pre-emption and field pre-emption principles." *Egelhoff*, 532 U.S. at 153 (Breyer, J., dissenting, joined by Stevens, J.). A field preemption approach would, for example, accord with the "rate regulation" rationale of *Travelers* and *Rutledge*. Those cases turned on the idea that, with ERISA's preemption clause, "Congress [did not intend] to displace general healthcare regulations" that have only an "indirect economic influence" on the cost of covered healthcare services. *Travelers*, 551 U.S. at 659-661. Because such laws do not regulate employee benefit plans themselves, field preemption would entail the same result.

b. Sections 16.1 and 16.2 are field-preempted in their entireties. They expressly attempt to supplement ERISA's comprehensive regulatory scheme relating to ERISA-covered prescription drug benefit plans. ERISA fully occupies that field (*Dillingham*, 519 U.S. at 336 (Scalia, J., concurring)), and this Court can and should say so expressly.

As a baseline matter, "nothing in ERISA requires employers to establish employee benefits plans," and "ERISA [does not] mandate what kind of benefits employers must provide if they choose to have such a plan." *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 833 (2003) (quoting *Lockheed Corp. v. Spink*, 517 U.S. 882, 887 (1996)). "Rather, employers have large leeway to design disability and other welfare plans as they see fit" under ERISA. *Id*. This is why states may not dictate benefit design.

At the same time, ERISA includes a detailed scheme of substantive rights and obligations and "an integrated system of procedures for enforcement." *Aetna Health*, 542 U.S. at 208. We already have shown that ERISA comprehensively regulates recordkeeping and disclosures, and transactions with interested third parties, including PBMs. Federal regulators have recently supplemented those standards. This extensive scheme of federal standards (including the considered absence of certain standards) demonstrates that ERISA and its implementing regulations fully occupy the field of laws regulating employee benefit plans. In this context, "Congress left no room for the States to supplement" federal requirements. *Cipollone v. Liggett Group*, 505 U.S. 504, 516 (1992).

Yet Sections 16.1 and 16.2 purport to do just that: They dictate rules for benefit design, impose state-specific reporting and disclosure requirements, and regulate plans' relationships with third parties. This, they may not do. To hold otherwise would be to invite states across the country to enact a patchwork of variable benefits regulations addressing varying local political interests—precisely the outcome that Congress, through ERISA, intended to prevent. "Congress intended pre-emption to afford employers the advantages of a uniform set of administrative procedures governed by a single set of regulations." *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 11 (1987). Under that rationale, Sections 16.1 and 16.2 are also field-preempted.

IV. MEDICARE PREEMPTS SECTIONS 16.1 AND 16.2 AS APPLIED TO PART D PLANS

Sections 16.1 and 16.2 are preempted as applied not only to ERISA-covered benefit plans, but also to benefit plans provided under the Medicare Part D program.

Medicare "preempts a state law when [federal authorities have] established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." *Rutledge*, 891 F.3d at 1113 (quoting 42 U.S.C. §1395w-26(b)(3)). Under this language, "conflict between the state law and the federal standard is unnecessary." *Id*.; *accord Uhm v. Humana*, 620 F.3d 1134, 1148-1150 (9th Cir. 2010). That is to say, express Medicare preemption is coextensive with field preemption: As the First Circuit has observed, "Congress's purpose in enacting § 1395w-26(b)(3) was to protect the purely federal nature of [benefit] plans operating under Medicare." *First Med.*, 479 F.3d at 52. Medicare's preemption clause (42 U.S.C. §§1395w-26(b)(3) and -112(g)) thus ensures that Medicare Part D remains a "federal program operated under Federal rules" and that "[s]tate laws, do not, and should not apply, with the exception of state licensing laws or state laws related to plan solvency." *Id*. at 51 (quoting H. Conf. Rep. 108-391, at 557, reprinted in 2003 U.S.C.C.A.N. 1808, 1926).

With respect to Sections 16.1 and 16.2, the Medicare scheme occupies the field in all relevant respects. It specifies that government authorities are

not to interfere in the negotiations with pharmacies; establishes a substantive standard for provider contracts; prohibits the imposition of standards for formularies or price and reimbursement structures; and sets up a reticulated scheme of federal regulations. Because Sections 16.1 and 16.2 purport to regulate in the same field and "with respect to" covered plans, they are preempted in their entireties as applied to Part D plans.

A. Sections 16.1 and 16.2 impermissibly supplement Medicare's exclusively federal regulatory scheme

This Court correctly held in *Rutledge* that Medicare preempts state laws that regulate in the same areas already covered by federal Medicare, akin to field preemption. Arkansas did not challenge that holding before the Supreme Court, raising only ERISA preemption. This Court's original decision in *Rutledge* thus continues to control for purposes of Medicare Part D preemption.

1. Federal network-pharmacy contract standards

The Medicare statute and its implementing regulations establish two standards concerning Part D plan contracts with pharmacies, either of which is sufficient to resolve the Medicare preemption claim in PCMA's favor. *First*, the Medicare statute requires that plan sponsors "permit the participation of any pharmacy that meets *the terms and conditions under the plan*." 42 U.S.C. §1395w-104(b)(1)(A) (emphasis added) (the any-willing-pharmacy standard). *Second*, a CMS regulation requires that the "terms and conditions" of a plan's

"standard contract" with "any willing pharmacy" be "*reasonable and relevant*." 42 C.F.R. §423.505(b)(18) (emphasis added). Because all aspects of Sections 16.1 and 16.2 impose various terms on Part D plan contracts with pharmacies, the challenged provisions fall squarely within this federal sphere.

As a preliminary matter, the district court was wrong that Medicare's federal standards have "no bearing on the negotiation and contracting process between pharmacies and PBMs." Add.20. Federal regulations specify expressly that when PBMs negotiate contracts with pharmacies, they stand in the shoes of the Part D plans that retain them. 42 C.F.R. §423.505(i) (providing that Part D plans must require downstream entities carrying out plan activities on their behalves to abide by the laws, rules, regulations, and contract terms applicable to the plan). Thus, federal standards regulating contracts between pharmacies and Part D plans apply equally when it is a PBM as third-party administrator contracting with pharmacies on behalf of those plans. *See Rutledge*, 891 F.3d at 1114 (holding that the federal pharmacy-access standard preempted the state law regulating contracts between pharmacies and PBMs).

a. The any-willing-pharmacy standard. Part D's any-willing-pharmacy standard requires plan sponsors to "permit the participation of any pharmacy that meets the terms and conditions under the plan." 42 U.S.C. §1395w-104(b)(1)(A). If a pharmacy does not meet a plan sponsor's terms and

conditions, then federal law allows the plan sponsor to deny the pharmacy's participation in its network. Sections 16.1 and 16.2 undermine that standard by forcing plans to allow pharmacies to participate even if they fail to meet the plan's terms and conditions.

The district court interpreted the purpose of this standard to "ensure patients have ready access to pharmaceutical services," but only based on the title of the Section. Add.19-20. "The title of a statute … cannot limit the plain meaning of the text.'" *Fla. Dep't of Revenue v. Piccadilly Cafeterias, Inc.*, 554 U.S. 33, 47 (2008). The any-willing-pharmacy standard presumes that a pharmacy cannot participate in a plan if the pharmacy refuses to meet the *plan's* terms and conditions. North Dakota's imposition of state-mandated terms and conditions is plainly a regulation operating "with respect to" Part D plans, triggering preemption.

b. The reasonable-and-relevant standard. CMS's reasonable-and-relevant standard requires that the "terms and conditions" of a plan's "standard contract" with "any willing pharmacy" be "reasonable and relevant." 42 C.F.R. §423.505(b)(18). CMS has explained that "a sponsor's standard terms and conditions establish 'a "floor" of minimum requirements that all similarly situated pharmacies must abide by' while sponsors may 'modify some of their standard terms and conditions to encourage participation by particular pharmacies.'" Memorandum from Amy K. Larrick, Acting Director, Medicare Drug Benefit and C&D Data Group, to All Medicare Part D Plan Sponsors:

Compliance with Any Willing Pharmacy (AWP) Requirements 1-2 (Aug. 13, 2015), perma.cc/67W8-YNB9. And "CMS maintains the authority to review all materials related to a sponsor's compliance with the [any-willing-pharmacy] requirement and may evaluate whether a sponsor's standard terms and conditions are reasonable and relevant." *Id.* at 2.

North Dakota, however, has purported to establish its own regulatory floor and ceiling "with respect to" Part D plans. Those state standards are "superseded" (42 U.S.C. §1395w-26(b)(3)) by federal law.

2. Federal non-interference standard

The two federal provisions we have just discussed are reason enough to conclude that Sections 16.1 and 16.2 invade a field left exclusively to federal regulation. But there are more.

Because the purpose of Medicare Part D was to ensure that market forces would operate freely to reach the optimal balance between cost and benefits, Congress expressly barred CMS from (a) interfering in negotiations between pharmacies and Medicare Part D plans, (b) requiring plans to adopt a particular formulary, or (c) instituting a price structure for the reimbursement of Part D drugs. *See* 42 U.S.C. §1395w-111(i). "The statute prohibits *both* federal and state interference in negotiations between Part D sponsors and pharmacies[.]" *Rutledge*, 891 F.3d at 1113 (emphasis added). Sections 16.1's and 16.2's regulations of pharmacy contracts intrude upon, and are therefore superseded by, this federal standard.

First, many provisions of Sections 16.1 and 16.2 interfere with contract negotiations between PBMs (on behalf of plan sponsors) and pharmacies by mandating or proscribing outcomes on issues that would otherwise be open to negotiation. For that reason alone, they are preempted. The district court thought the non-interference standard did not apply because it does not facially include PBMs, applying instead only to plan sponsors and pharmacies. Add.21-22. Again, that is wrong. *See* 42 C.F.R. §423.505(i).

Second, Section 16.2(5) appears to require that a Part D plan reimburse a pharmacy for dispensing "any and all drugs allowed under [its] license," which would effectively outlaw formularies and other tools like preauthorization. The non-interference standard prohibits the government from requiring a formulary or instituting a pricing structure, thus requiring preemption. The district court did not address this argument.

Third, Section 16.1's provisions specifying which fees a pharmacy may or may not be charged (Sections 16.1(3), (9)) and setting a price ceiling for drug charges to Part D beneficiaries (Section 16.1(4)) purport to establish a price structure for Part D plans. That, too, is expressly forbidden by the non-interference clause. The district court did not address this argument.

Congress established the non-interference standard for pharmacy negotiations, formulary development, and a pricing structure. Sections 16.1 and 16.2 intrude on these areas of regulation "with respect to" Part D plans. They are therefore preempted by federal law.

3. Other federal standards

The three federal provisions we have just discussed compel preemption of Sections 16.1 and 16.2 because they invade areas of regulation controlled exclusively by federal law. In numerous additional respects, Sections 16.1 and 16.2 "detract[] from the integrated scheme of regulation created by Congress" by regulating in areas where detailed, reticulated federal standards already exist. *Arizona*, 567 U.S. at 402.

To be clear, a state standard need not overlap with a federal standard for the state standard to regulate "with respect to" a Part D plan within the meaning of Section 1395w-26(b)(3). *Cf. Puerto Rico Dep't of Consumer Affs. v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988) (when there is a "comprehensive federal scheme," field preemption applies to both regulatory "action" and "inaction"). Nonetheless, overlap with a federal standard is unassailable proof of preemption.

Section 16.2(5)'s authorization to pharmacies to dispense "any and all" drugs. Section 16.2(5) mandates that pharmacies must be permitted to "dispense any and all drugs allowed under that license." To the extent this language means that Part D plans (or their PBMs) must allow pharmacies to dispense "any and all" drugs as *covered* drugs, it is preempted.

A formulary is a list of drugs that a Part D plan covers. 42 C.F.R. §423.4. CMS extensively regulates formularies. *See id.* §423.120(b) (detailing "[f]ormulary requirements"). Further, CMS regulates the substantive make-

up of formularies. *See id.* §423.120(b)(2) (listing types of drugs that must be on a formulary). Most importantly, CMS approves both particular drugs on the formulary and the formulary as a whole. *See id.* §423.120(b)(2)(ii); *accord id.* §423.120(b)(2)(iv) (plan's formulary must "[b]e approved by CMS"). Allowing North Dakota pharmacies to ignore formularies would undermine CMS's contemplation, regulation, and approval of them.

Sections 16.1(8)'s and (9)'s regulation of mail-service benefits and shipping fees. Section 16.1(8) authorizes pharmacies to "mail or deliver drugs to a patient as an ancillary service," and Section 16.1(9) prohibits PBMs from "prohibit[ing] a pharmacist … from charging a shipping and handling fee."

CMS already regulates pharmacies' mailing and delivering of Part D-covered drugs. For example, CMS allows plans to impose reasonable and relevant standard terms and conditions on pharmacies that mail prescriptions. 83 Fed. Reg. 16,440, 16,594-16,595 (Apr. 16, 2018). But CMS also determined that specialty pharmacies must be able to mail prescriptions without meeting the terms and conditions for mail-service benefits. *Id.* Sections 16.1(8)-(9) substantially overlap with these Part D regulations, compelling preemption.

CMS also regulates the payment of dispensing fees, including "pharmacy costs associated with ensuring that … the appropriate covered Part D drug is transferred to a Part D enrollee," for example, "delivery" costs. 42

C.F.R. §423.100. As Sections 16.1(8)-(9) regulate mail-service access and shipping and handling fees, which Medicare Part D already regulates, they are preempted.

Sections 16.1(5)'s and (7)'s regulation of the disclosure of reimbursement information. Section 16.1(5) provides that a pharmacy "may disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement," and Section 16.1(7) mandates that a pharmacy "may provide relevant information to a patient."

Medicare establishes a comprehensive federal system for disclosure of information to Part D plan members. First, federal law provides that a Part D sponsor "shall provide that each pharmacy that dispenses a covered part D drug shall inform an enrollee of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan." 42 U.S.C. §1395w-104(k)(1). Thus, Congress has already decided what drug-pricing or other information a pharmacy shall provide to a plan member.

Medicare Part D also requires Part D plans to make various disclosures to plan members. *See* 42 U.S.C. §1395w-104(a)(1). Thus, Part D already comprehensively regulates disclosures to plan members.

The case for preemption here has recently strengthened: Congress enacted 42 U.S.C. §1395w-104(m), which provides that Part D plans cannot "restrict a pharmacy that dispenses a prescription drug or biological from

informing, nor penalize such pharmacy for informing, an enrollee in such plan of any differential between the negotiated price of, or copayment or coinsurance for, the drug" and "a lower price the individual would pay for the drug or biological if the enrollee obtained the drug without using any health insurance coverage." *See* 42 U.S.C. §1395w-104(m). This new provision further confirms Sections 16.1(5) and (7) invade areas within exclusive federal control.

Section 16.1(10)'s regulation of PBM disclosures. Under Section 16.1(10), "a [PBM or plan] shall provide a pharmacy or pharmacist with the processor control number, bank identification number, and group number for each pharmacy network established or administered by a [PBM]."

The Medicare statute and its implementing regulations govern PBMs' disclosure of information regarding pharmacy networks. *See, e.g.*, 42 C.F.R. §423.514(d). For example, the Part D statute requires PBMs to disclose to the Secretary the total number of prescriptions dispensed; the generic-drug dispense rate; the amount and type of rebates, discounts, or price concessions earned; and the amount of the difference between what the plan paid and pharmacies received. 42 U.S.C. §1320b-23.

The Secretary and plans must keep the PBM disclosures confidential, unless the Secretary determines that broader disclosure is "necessary to carry out this section or part D[.]" 42 U.S.C. §1320b-23(c). Further, CMS requires plans to disclose to CMS all "4Rx data which is the RxBIN [bank identi-

fication number], Processor Control Number (PCN), Group ID (RxGRP) and Cardholder ID (RxID)," including by regulating what must appear on participant ID cards. CMS, Part D Benefit Manual, ch. 14, §50.1 (PDB Manual). Section 16.1(10) regulates with respect to these same areas and is therefore preempted.

The district court held that these federal standards relate to PBM disclosures to plans, the Secretary, and plan members, but not to pharmacies. That misses the point. These federal standards already regulate the form and substance of disclosures of the information covered by Section 16.1(10). States cannot supplement or override that federal judgment.

Section 16.1(3)'s regulation of pharmacy performance standards. Section 16.1(3) requires PBMs to use EQuIPP or "other unbiased nationally recognized entity aiding in improving pharmacy performance measures"; prohibits PBMs from collecting a performance-based fee for pharmacies that satisfy the third-party's standards; limits PBMs "to applying the fee to the professional dispensing fee" if performance standards are not met; and prohibits "fee[s] relating to performance metrics on the cost of goods sold." These requirements all overlap with various federal standards, which require that plans—with and through their PBMs—have programs designed to encourage cost-effective drug utilization and quality-assurance measures.

For instance, the Part D statute provides that plan sponsors must have "[a] cost-effective drug utilization management program" and "quality assur-

ance measures and systems to reduce medication errors and adverse drug interactions and improve medication use." 42 U.S.C. §1395w-104(c). Further, CMS regulations require quality measures above and beyond state pharmacy licensing standards. CMS requires that Part D plans have "established quality assurance measures and systems" that include requiring "network providers … to comply with minimum standards for pharmacy practice," "[c]oncurrent drug utilization review systems," "[r]etrospective drug utilization review systems," and "[i]nternal medication error identification and reduction systems." 42 C.F.R. §423.153(c).

In short, the Part D statute *requires* plans and PBMs to implement performance standards and CMS regulations include substantive criteria for those performance standards. Sections 16.1 and 16.2 cannot supplement or override these federal criteria by providing that pharmacies must satisfy only state pharmacy standards.

Much the same goes for performance-based fees, which help ensure cost-effective drug utilization and quality. Performance-based fees, by their nature, cannot be calculated at the time of processing. And CMS regulations expressly contemplate the payment of post-point-of-sale direct and indirect remuneration. *E.g.*, 42 C.F.R. §423.308. Federal regulations also expressly distinguish between these post point-of-sale performance fees and dispensing fees. *See id.* §423.100 (defining "negotiated prices" to "[i]nclude any dispensing fees" but to "[e]xclude[] additional contingent amounts, such as

incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale"). Thus, performance fees are also squarely within the field of federal regulation.

Finally, dispensing fees are expressly included in a Part D plan's allowable risk corridor costs. *See* 42 C.F.R. §423.308. Because Sections 16.1(3) and 16.1(11) regulate performance standards and fees that Medicare Part D already regulates, Part D preempts them.

Sections 16.1(11)'s and 16.2(4)'s regulation of pharmacy accreditation standards. Sections 16.1(11) and 16.2(4) prohibit a PBM from requiring a pharmacy to comply with accreditation standards "more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in" North Dakota. As discussed above, Part D standards require plan sponsors to "permit the participation of any pharmacy that meets the terms and conditions under the plan." 42 U.S.C. §1395w-104(b)(1)(A).

The district court rejected PCMA's argument concerning Section 16.1(11), largely relying on CMS's response to a comment expressing concern about Sections 16.1 and 16.2, which the district court interpreted as CMS's approval of Section 16.1(11). But CMS's response—that "state pharmacy practice acts represent a reasonably consistent minimum standard of practice" (83 Fed. Reg. at 16,598)—has no application to Section 16.1(11), which sets a ceiling, not a floor, for Part D network pharmacy accreditation.

Indeed, CMS "agree[s] that there is a role in the Part D program for pharmacy accreditation, to the extent pharmacy accreditation requirements in network agreements promote quality assurance." 83 Fed. Reg. at 16,597. CMS also "reiterate[d] … that we support Part D plan sponsors that want to negotiate an accreditation requirement" for preferred network status. *Id.* at 16,598. North Dakota's attempt to regulate pharmacy accreditation requirements for Part D plans is thus preempted.

Section 16.1(2)'s limits on retroactive fees. Section 16.1(2) prohibits plans and PBMs from "directly or indirectly charg[ing] or hold[ing] a pharmacy responsible for a fee related to a claim" that is (a) "not apparent at the time of claim processing"; (b) "not reported on the remittance advice of an adjudicated claim"; or (c) "after the initial claim is adjudicated at the point of sale."

CMS *requires* plans to recoup retroactive payments from pharmacies in certain circumstances, *prohibits* plans from recouping retroactive payments from pharmacies in other circumstances, and *allows* plans to collect retroactive fees in yet other circumstances so long as the plan discloses it. Part D plans "must comply with all administrative processes and requirements established by CMS" concerning coordination of benefits between plans and certain entities regarding "[r]etroactive claims adjustments, underpayment reimbursements, and overpayment recoveries." 42 C.F.R. §423.464(a).

For example, plans must recoup the cost of the drug or claim when certain coverage errors are committed. *See* Memorandum from Cheri Rice to All Medicare Part D Sponsors: PDE Guidance for Post Point-of-Sale Claim Adjustments 2 (July 3, 2013), perma.cc/5ECY-83N8. But in other circumstances, plans are prohibited from "requesting pharmacy claims reversal and re-adjudication." 42 C.F.R. §423.464(f)(6).

In yet other circumstances, CMS allows a plan to charge pharmacies retroactive fees but requires plans to report post point-of-sale fees to CMS by requiring them to report amounts "actually paid" for the drugs and the "direct and indirect remuneration" (DIR) a plan has received. *See* 42 C.F.R. §423.322(a). CMS regulations contemplate the payment of "direct and indirect remuneration" that is made after the point of sale. *See* 42 C.F.R. §423.100 (defining "negotiated prices" to "[e]xclude[] additional contingent amounts, such as incentive fees"). "Examples of [post point-of-sale] compensation include … concessions paid by pharmacies. Under Medicare Part D, this post point-of-sale compensation is called Direct and Indirect Remuneration (DIR) and is factored into CMS's calculation of final Medicare payments to Part D plans." CMS, Medicare Part D - Direct and Indirect Remuneration (DIR) (Jan. 19, 2017), perma.cc/82BU-U3BP.

At the end of a contract year, through a reconciliation process, CMS makes final reinsurance and risk corridor payments to Part D sponsors based

on the amounts "actually paid" by the Part D sponsor for the provision of the Part D benefit. *See* 42 C.F.R. §§423.308, 423.336(b).

Section 16.1(2)'s attempt to impose a blanket ban on plans recouping retroactive fees intrudes on this area of federal concern.

The district court held that Section 16.1(2) would not alter "the calculations used in the reconciliation process." Add.30. But that is wrong. Eliminating one source of DIR for sponsors, as Section 16.1(2) does, means CMS may ultimately need to pay plans more to make up for that lost revenue. In any event, the federal regulations mandating disclosure preempt Section 16.1(2) regardless of whether reconciliation payments are affected. *See John Doe No. 1 v. Reed*, 561 U.S. 186, 213 (2010) (Sotomayor, J., concurring) (noting disclosure is a type of regulation).

Section 16.1(4)'s regulation of copayments and adjudicated costs. Section 16.1(4) provides that "[i]f a patient pays a copayment, the … pharmacy shall retain the adjudicated cost," apparently barring PBMs from recouping copayment amounts. It also prohibits PBMs from redacting the adjudicated cost.

Federal regulations regulate cost sharing, including copays. When a plan member is under the initial coverage limit, the copayment a plan charges must be "[e]qual to 25 percent of [the drug's] actual cost." 42 C.F.R. §423.104(d)(2)(i)-(ii). After a plan member exceeds a specific out-of-pocket amount, "[c]opayments" for the member must be "$2 for a generic drug or

preferred drug … and $5 for any other drug." *Id.* §423.104(d)(5)(i)(A). CMS regulations also contemplate that PBMs, for plan sponsors, will collect copays. *See id.* §423.800(c) (sponsors must return excess cost-sharing amounts to subsidized, low-income participants); *see also* PDB Manual, ch. 13, §70.3.1 (requiring plans to collect copayments from beneficiaries ineligible for subsidies).

In refusing preemption on this point, the district court faulted PCMA for not identifying federal standards that specify who retains the copayment. Add.31. But the district court failed to consider the broad-based federal regulations concerning cost-sharing generally. Here, again, North Dakota Section 16.1(4) has intruded on an area of exclusive federal concern "with respect to" Part D plans and is preempted.

Section 16.2(3)'s conflict-of-interest and third-party limitations. Section 16.2(3) prohibits PBMs from "hav[ing] an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the [PBM] agrees to not participate in a transaction that benefits the [PBM] instead of another person owed a fiduciary duty."

Like ERISA, Medicare regulations contemplate interested-party transactions and regulates their use and disclosure of such use. *See* 42 C.F.R. §423.501 (defining "[r]elated entity" as having common ownership or control as the plan sponsor and contemplating that such entities may "perform[] some of the Part D plan sponsor's management functions … [or] [f]urnish[]

services to Medicare enrollees"). CMS regulates plan sponsor management controls, including measures intended to avoid conflicts of interest. *E.g.*, 42 C.F.R. §423.504(b)(4)(vi)(G), -(b)(10), -(e)(2).

The conduct that CMS and North Dakota both seek to prevent is self-dealing. But the district court held that there are no federal standards regulating this subject matter. Add.34. Of course, that alone is not enough to deny preemption. But even if it were, the federal regulations identified above regulate potential conflicts of interest. In all events, the point is simply that Section 16.2(3) regulates with respect to Part D plans and their relationships with PBMs; it is therefore preempted.

B. Sections 16.1 and 16.2 have an impermissible "connection with" Part D plans

We have shown in detail how Medicare and CMS's implementing regulations fully occupy the field of regulation in which Sections 16.1 and 16.2 purport to add state standards. They are therefore preempted under a straightforward field preemption analysis, of the sort applied by this Court in *Rutledge*. Alternatively—using a similar analytical framework as ERISA preemption—Sections 16.1 and 16.2 are preempted because they have a "connection with" Part D plans.

In considering the scope of an express-preemption provision, a court should "in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent." *CSX*

Transp., Inc. v. Easterwood, 507 U.S. 658, 664 (1993). For that reason, in *Morales v. Trans World Airlines*, 504 U.S. 374 (1992), the Supreme Court held that the Airline Deregulation Act's (ADA) express-preemption provision should be interpreted in the same manner as ERISA's provision, in light of their similar language. *Id*. at 384-385. In particular, Congress's use in the ADA of the words "relating to" were held to be sufficiently similar to the language of ERISA's preemption clause ("relate to") that the same analytical test should apply. *See Morales*, 504 U.S. at 383-86.

The same logic applies here: The concept of standards "with respect to MA plans" within the meaning of 42 U.S.C. §1395w-26(b)(3) is analytically the same as the concept of standards that "relate to any employee benefit plan" within the meaning of 29 U.S.C. §1144(a). As the First Circuit has explained in a different legal context, "courts describe the phrase 'with respect to' as synonymous with the phrases 'with reference to,' 'relating to,' 'in connection with,' and 'associated with.'" *Huffington v. T.C. Grp., LLC*, 637 F.3d 18, 22 (1st Cir. 2011). Accordingly, the same preemption framework that applies under ERISA can alternatively apply under Medicare.[3]

[3] That said, *Traveler*'s and *Rutledge*'s rationale for excluding "rate regulation" from ERISA's preemptive scope would not apply to Medicare because pharmacy rate regulation is central to, and an essential part of, Medicare's regulation of Part D plans.

C. Sections 16.1 and 16.2 are not saved from preemption.

In rejecting PCMA's Medicare preemption arguments, the district court invoked two saving clauses. But neither the practice-of-medicine clause nor the licensing exception saves the challenged provisions from preemption.

1. The practice-of-medicine clause

The district court reasoned that various provisions of Sections 16.1 and 16.2 were saved from Part D preemption by the practice-of-medicine saving clause, 42 U.S.C. §1395. *See* Add.22, Add.25. That is incorrect.

Section 1395 states that "[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." 42 U.S.C. §1395.

As an initial matter, Section 1395 does not limit the preemptive effect of §§1395w-26(b)(3) and 1395w-112(g). Rather, it limits the control of federal officers over medical practitioners, not the preemptive effect of federal standards upon statutes enacted by states.

Beyond that, the district court misunderstood the distinction between substantive medical care and insurance for such care. If a Part D plan does not cover a particular pharmacy's dispensing of a drug, that is not supervision over *how* a pharmacy provides its services—the plan participant is free to request, and the pharmacist is free to dispense, any drug at any time under any circumstance. A plan cannot dictate whether a patient may use an

out-of-network provider, nor can it tell a doctor or pharmacist not to administer medical care. All it can do is decline to reimburse a plan participant for a prescription drug acquired under non-covered circumstances (such as from an out-of-network provider).

And even if Section 1395 were relevant here, the district court conflated "practice of pharmacy" with "practice of medicine." North Dakota law defines the two separately. *See* N.D. Cent. Code §43-17-01(5) (defining "Practice of medicine"); N.D. Cent. Code §43-15-01(24) (defining "Practice of pharmacy"). What pharmacists and physicians practice are distinct, and the district court failed to explain how a regulation of the former is equivalent to a regulation of the latter within the meaning of Section 1395.

2. The licensing exception

Nor can Medicare Part D's licensing exception save any of the challenged provisions from preemption, for two reasons.

First, Medicare preemption's licensing exception saves only "State licensing laws ... with respect to [Part D] *plans*." 42 U.S.C. §1395w-26(b)(3). That is a reference to state laws that regulate Part D plans, not pharmacies. CMS has confirmed this reading, recognizing that "State laws and regulations that are not pre-empted because they relate to 'State licensing' are limited to State requirements for *becoming State licensed*, and do not extend to any requirement that the State might impose *on licensed health plans*[.]" CMS, Medicare Managed Care Manual, ch. 10, §30.1 (emphases added).

Accordingly, no provision of Sections 16.1 or 16.2 is a licensing law saved from federal preemption because none purports to license a Part D plan.

Second, even if Medicare preemption's licensing exception could extend to state licensing of entities other than plans, Sections 16.1 and 16.2 are still not *licensing* laws. That much is clear because Sections 16.1 and 16.2 do not mention licensing at all, except mentioning pharmacist licenses in passing to allow pharmacists to dispense any and all drugs. Simply put, these are not "state licensing laws," even of pharmacies, within the meaning of Section 1395w-26(b)(3).

CONCLUSION

The Court should reverse and remand with instructions to enter judgment declaring that Sections 16.1 and 16.2 are expressly preempted as applied to ERISA-covered plans and Part D plans.

Respectfully submitted,

Dated: May 10, 2021

/s/ *Michael B. Kimberly*

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(g) and 8th Circuit R. 28A(h)(2), I hereby certify that:

(i) this brief complies with the word limit of Fed. R. App. P. 29(a)(5) because it contains 12,819 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f);

(ii) this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6); and

(iii) the electronic brief has been scanned for viruses using Windows Defender and found to be virus free.

Dated: May 10, 2021 /s/ *Michael B. Kimberly*

CERTIFICATE OF SERVICE

I hereby certify that on May 10, 2021, I electronically filed the foregoing brief with the Clerk of this Court using the CM/ECF system, and counsel for all parties will be served by the CM/ECF system.

/s/ *Michael B. Kimberly*