NAIC NATIONAL MEETING FALL 2021

Revised: 12/6/21

2021 Fall National Meeting
San Diego, California

PHARMACY BENEFIT MANAGER REGULATORY ISSUES (B) SUBGROUP
Saturday, December 11, 2021
2:15 – 3:15 p.m.
San Diego Convention Center—Room 29—Upper Level

ROLL CALL

TK Keen, Chair	Oregon
Laura Arp, Vice Chair	Nebraska
Anthony L. Williams	Alabama
Lori K. Wing-Heier/Chris Murray/Sarah Bailey	Alaska
Beth Barrington	Arkansas
Bruce Hinze	California
Paul Lombardo/Kathy Belfi	Connecticut
Howard Liebers	District of Columbia
Andria Seip	Iowa
Vicki Schmidt	Kansas
Daniel McIlwain	Kentucky
Jeff Zewe	Louisiana
Mary Kwei	Maryland
Chad Arnold	Michigan
Andrew Kleinendorst	Minnesota
Chlora Lindley-Myers/Amy Hoyt	Missouri
David Dachs	Montana
Gale Simon	New Jersey
Renee Blechner/Margaret Pena	New Mexico
Robert Croom	North Carolina
Michael Humphreys	Pennsylvania
Katrina Rodon	South Carolina
Brian Hoffmeister	Tennessee
Tanji J. Northrup	Utah
Don Beatty	Virginia
Jennifer Kreitler/Ron Pastuch/Ned Gaines	Washington
Ellen Potter	West Virginia
Nathan Houdek	Wisconsin
Denise Burke	Wyoming

NAIC Staff Support: Jolie H. Matthews

AGENDA

1. Hear an Update on the *Pharmaceutical Care Management Association (PCMA) v. Wehbi* Ruling —*Commissioner Jon Godfread (ND)*

2. Hear from States on Implementation of Pharmacy Benefit Manager (PBM) Laws —*TK Keen (OR)*
   A. Connecticut—*Paul Lombardo (CT)*
   B. Oklahoma—*Kelli Price (OK)*
   C. Virginia—*Don Beatty (VA)*
   D. Wisconsin—*Nathan Houdek (WI)*

3. Discuss Work Plan for Completing White Paper Charge—*TK Keen* (OR)

4. Discuss Any Other Matters Brought Before the Subgroup—*TK Keen (OR)*

5. Adjournment

PBM Subgroup Agenda

Agenda Item #1

Hear an Update on the
Pharmaceutical Care Management Association (PCMA) v. Wehbi Ruling
—Commissioner Jon Godfread (ND)

United States Court of Appeals
For the Eighth Circuit

No. 18-2926

Pharmaceutical Care Management Association

Plaintiff - Appellant

v.

Nizar Wehbi, in his official capacity as the State Health Officer of North Dakota; Mark J. Hardy, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy; Tyler Lannoye, in his official capacity as the President of the North Dakota Board of Pharmacy; Wayne Stenehjem, in his official capacity as the Attorney General of North Dakota

Defendants - Appellees

The Chamber of Commerce of the United States of America; America's Health Insurance Plans; Association of Federal Health Organizations

Amici on Behalf of Appellant(s)

National Association of Chain Drug Stores; National Council of Insurance Legislators; State of Minnesota; State of Alaska; State of Arizona; State of Arkansas; State of California; State of Colorado; State of Connecticut; State of Delaware; State of Georgia; State of Hawaii; State of Illinois; State of Indiana; State of Maine; State of Maryland; State of Massachusetts; State of Michigan; State of Mississippi; State of Nebraska; State of Nevada; State of New Jersey; State of New Mexico; State of New York; State of North Carolina; State of Oklahoma; State of Oregon; State of Rhode Island; State of South Carolina; State of South Dakota; State of Texas; State of Utah; State of Vermont; State of Virginia; State of Washington; District of Columbia; National Community Pharmacists Association; American Pharmacists Association; North Dakota

Pharmacists Association; Arkansas Pharmacists Association; Iowa Pharmacists Association; Minnesota Pharmacists Association; Missouri Pharmacists Association; Nebraska Pharmacists Association; South Dakota Pharmacists Association; Alliance for Transparent and Affordable Prescriptions; Community Oncology Alliance; American Pharmacies

Amici on Behalf of Appellee(s)

Appeal from United States District Court
for the District of North Dakota - Bismarck

Submitted: September 1, 2021
Filed: November 17, 2021

Before SMITH, Chief Judge, GRUENDER and BENTON, Circuit Judges.

GRUENDER, Circuit Judge.

Pharmaceutical Care Management Association ("PCMA") sued to enjoin the enforcement of several North Dakota statutory provisions, claiming that they were preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 *et seq.* The district court concluded that ERISA preempted none of the challenged provisions and that Medicare Part D preempted only one. *Pharm. Care Mgmt. Ass'n v. Tufte*, 326 F. Supp. 3d 873 (D.N.D. 2018), *aff'd in part, rev'd in part*, 968 F.3d 901 (8th Cir. 2020), *vacated sub nom. Wilke v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 1364 (2021) (mem.). PCMA appealed, and we reversed on the issue of ERISA preemption. *Tufte*, 968 F.3d 901. Subsequently, the Supreme Court vacated our judgment and remanded for us to reconsider the case in light of *Rutledge v. Pharmaceutical Care Management Association*, 592 U.S. ---, 141 S. Ct. 474 (2020). *Wilke*, 141 S. Ct. 1364. Having done so, we affirm in part and reverse in part.

I.

In 2017, North Dakota enacted two laws, codified at North Dakota Century Code sections 19-02.1-16.1 and -16.2. The laws regulate entities known as "pharmacy benefits managers" ("PBMs") that manage prescription-drug benefits on behalf of health-insurance plans. The relevant provisions in section 16.1 read as follows:

> 2. A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:
>
> a. That is not apparent at the time of claim processing;
>
> b. That is not reported on the remittance advice of an adjudicated claim; or
>
> c. After the initial claim is adjudicated at the point of sale.
>
> 3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
>
> a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
>
> b. If a pharmacy benefits manager or third-party payer imposes a fee upon a pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-

party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.

c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.

4. . . . . If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

5. . . . . A pharmacy or pharmacist may disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement paid to the pharmacy which is compliant under the federal Health Insurance Portability and Accountability Act of 1996 [Pub. L. 104-191; 110 Stat. 1936; 29 U.S.C. 1181 et seq.].

. . .

7. A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.

8. A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy.

9. A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered.

10. Upon request, a pharmacy benefits manager or third-party payer 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 pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

11. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

The relevant provisions in section 16.2 read as follows:

2. If requested by a plan sponsor contracted payer, a pharmacy benefits manager or third-party payer that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer.

3. A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.

4. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.

5. A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license.

Shortly after these laws were enacted, PCMA—a national trade association representing PBMs—sued various North Dakota officials in their official capacities. PCMA asked the district court to enjoin the enforcement of the provisions reproduced above on the ground that they are preempted by ERISA and Medicare Part D.

Both parties moved for summary judgment. The district court held that Medicare Part D preempted section 16.2(2) as applied to Medicare Part D plans but otherwise rejected PCMA's challenges. *Tufte*, 326 F. Supp. 3d 873. PCMA appealed, and we reversed on the issue of ERISA preemption. *Tufte*, 968 F.3d 901. The defendants petitioned the Supreme Court for a writ of *certiorari*. While the defendants' petition was pending, the Court decided *Rutledge*, where it overturned the precedent that we had relied on to conclude that ERISA preempted the laws at issue here. *See Rutledge*, 141 S. Ct. at 479, 481; *Tufte*, 968 F.3d at 904-06. The Court then granted the defendants' *certiorari* petition, vacated our judgment, and remanded for us to reconsider the case in light of *Rutledge*. *Wilke*, 141 S. Ct. 1364.

In the meantime, Congress passed the Know the Lowest Price Act of 2018, Pub. L. No. 115-262, 132 Stat. 3670 (codified at 42 U.S.C. § 1395w-104(m)). The defendants concede that this statute preempts section 16.1(7) and the challenged portions of section 16.1(5) as applied to Medicare Part D plans. The defendants also now concede that section 16.1(2)(c) is preempted as applied to Medicare Part D plans. For its part, PCMA has withdrawn its claims that ERISA preempts section 16.1(2), section 16.1(3), the challenged portions of section 16.1(4), and section 16.2(5).

II.

We review *de novo* the district court's grant of summary judgment. *Bruning v. City of Omaha*, 6 F.4th 821, 824 (8th Cir. 2021). "Summary judgment is appropriate if the movant is entitled to judgment as a matter of law even when all genuine factual disputes are resolved in the nonmovant's favor." *Id.*

Before analyzing ERISA preemption in Section III and Medicare Part D preemption in Section IV, we resolve two disputes that implicate both issues. First, the parties dispute whether the challenged provisions escape preemption to the extent that they regulate PBMs rather than plans. We agree with PCMA that the challenged provisions do not escape preemption on this basis. Because PBMs

manage benefits on behalf of plans, a regulation of PBMs "function[s] as a regulation of an ERISA plan itself." *Pharm. Care Mgmt. Ass'n v. District of Columbia*, 613 F.3d 179, 188 (D.C. Cir. 2010); *see also Kollman v. Hewitt Assocs., LLC*, 487 F.3d 139, 148 (3d Cir. 2007) (explaining that the concerns underlying regulation of "ERISA plan managers" are "equally applicable to agents . . . who undertake and perform administrative duties for and on behalf of ERISA plans"). Therefore, the fact that, facially, the challenged provisions mostly regulate PBMs whereas ERISA and Medicare Part D mostly regulate plans does not mean that the challenged provisions escape preemption. *See District of Columbia*, 613 F.3d at 188 (concluding that ERISA preempted some of the District of Columbia's regulations of PBMs).

Second, the parties dispute whether we should invoke a presumption against preemption in this case given that both ERISA and Medicare Part D feature express preemption provisions. The defendants rely on a line of Supreme Court cases invoking a presumption against preemption in the face of an express preemption provision. *See, e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484-85 (1996) (addressing preemption under 21 U.S.C. § 360k(a)); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins.*, 514 U.S. 645, 654-55 (1995) (addressing ERISA preemption). According to PCMA, however, the Court overruled these cases in *Puerto Rico v. Franklin California Tax-Free Trust*, where it stated that "because [11 U.S.C. § 903(1)] contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause." 579 U.S. ---, 136 S. Ct. 1938, 1946 (2016) (internal quotation marks omitted).

Again, we agree with PCMA. The defendants argue that because *Franklin* did not expressly overrule prior precedent, we should not extend it to express preemption provisions such as ERISA's that the Court has historically treated as subject to a presumption against preemption. *See Rodriguez de Quijas v. Shearson/Am. Express, Inc.*, 490 U.S. 477, 484 (1989) ("If a precedent of this Court has direct application in a case, yet appears to rest on reasons rejected in some other

line of decisions, the Court of Appeals should follow the case which directly controls, leaving to this Court the prerogative of overruling its own decisions."). But in *Watson v. Air Methods Corp.*, we extended *Franklin* to the express preemption provision in 49 U.S.C. § 41713(b)(1), *see* 870 F.3d 812, 817 (8th Cir. 2017) (en banc); *accord EagleMed LLC v. Cox*, 868 F.3d 893, 899, 903 (10th Cir. 2017), despite indications that prior to *Franklin* the Court treated § 41713(b)(1) as subject to a presumption against preemption, *see, e.g.*, *Am. Airlines, Inc. v. Wolens*, 513 U.S. 219, 237 (1995) (Stevens, J., concurring in part and dissenting in part); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 419-20 (1992) (Stevens, J., dissenting). So too here, we will follow *Franklin* and invoke no presumption against preemption when applying the express preemption provisions in ERISA and Medicare Part D. *See Dialysis Newco, Inc. v. Cmty. Health Sys. Grp. Health Plan*, 938 F.3d 246, 258-59 (5th Cir. 2019) (extending *Franklin* to ERISA); *Snyder v. Prompt Med. Transp., Inc.*, 131 N.E.3d 640, 652 (Ind. Ct. App. 2019) (extending *Franklin* to Medicare Part C).

III.

ERISA "supersede[s] any and all State laws insofar as they may now or hereafter relate to any" ERISA plan. 29 U.S.C. § 1144(a). The Supreme Court has held that a law "relate[s] to" an ERISA plan if and only if it "has a connection with or reference to such a plan." *Rutledge*, 141 S. Ct. at 479. PCMA bears the burden of proving preemption. *See Williams v. Nat'l Football League*, 582 F.3d 863, 880 (8th Cir. 2009).

A.

A state law has an impermissible "connection with" ERISA plans if and only if (1) it "governs . . . a central matter of plan administration"; (2) it "interferes with nationally uniform plan administration"; or (3) "acute, albeit indirect, economic effects" of the law "force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers." *Gobeille v. Liberty Mut. Ins.*,

577 U.S. 312, 320 (2016). The mere fact that a state law "affects an ERISA plan or causes some disuniformity in plan administration" does not entail that the law meets this standard, "especially . . . if a law merely affects costs." *Rutledge*, 141 S. Ct. at 480. Instead, the connection-with standard is "primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status." *Id.* (citations omitted).

None of the challenged provisions meets the connection-with standard. Several of the provisions merely authorize pharmacies to do certain things—disclose certain information to the plan sponsor, § 16.1(5), "provide relevant information to a patient," § 16.1(7), "mail or deliver drugs to a patient as an ancillary service," § 16.1(8), and "charg[e] a shipping and handling fee to a patient requesting a prescription be mailed or delivered," § 16.1(9). These provisions affect PBMs only insofar as they prevent PBMs from preventing pharmacies from engaging in these practices. This constitutes, at most, a regulation of a noncentral "matter of plan administration" with *de minimis* economic effects and impact on the uniformity of plan administration across states. *See Gobeille*, 577 U.S. at 320; *cf. Rutledge*, 141 S. Ct. at 482 (holding that ERISA permits states to "allow[] pharmacies to decline to dispense a prescription if the PBM's reimbursement will be less than the pharmacy's cost of acquisition"). Certainly, it does not constitute "requiring payment of specific benefits," *Rutledge*, 141 S. Ct. at 480; the fact that a PBM must permit a pharmacy to fulfill mail orders or dispense all drugs allowed under its license does not mean that the PBM must *cover* mail orders or all drugs allowed under the pharmacy's license. Nor does it "bind[] plan administrators to specific rules for determining beneficiary status." *See id.* Therefore, section 16.1(7), section 16.1(8), section 16.1(9), and the challenged portions of section 16.1(5) do not have an "impermissible connection with" an ERISA plan. *See id.* at 478.

Sections 16.1(11) and 16.2(4) do not meet the connection-with standard, either. These provisions merely limit the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network. Again,

this constitutes, at most, regulation of a noncentral "matter of plan administration" with *de minimis* economic effects. *See Gobeille*, 577 U.S. at 320. It is possible that sections 16.1(11) and 16.2(4) will "cause[] some disuniformity in plan administration" by requiring PBMs to maintain different accreditation requirements in different states. *See Rutledge*, 141 S. Ct. at 480. But they do not "requir[e] payment of specific benefits" or "bind[] plan administrators to specific rules for determining beneficiary status." *See id.* Therefore, whatever modest disuniformity in plan administration sections 16.1(11) and 16.2(4) might cause does not warrant preemption. *See id.*

Nor do sections 16.1(10) and 16.2(2) meet the connection-with standard. These provisions require PBMs to disclose basic information to pharmacies and plan sponsors upon request. Again, such modest disclosure requirements constitute, at most, regulation of a noncentral "matter of plan administration" with *de minimis* economic effects and impact on the uniformity of plan administration across states. *See Gobeille*, 577 U.S. at 320; *cf. Self-Ins. Inst. of Am., Inc. v. Snyder*, 827 F.3d 549, 557-58 (6th Cir. 2016) (concluding that ERISA did not preempt a state law that "touch[ed] upon reporting and record-keeping" but was not designed "to amass data"); *Liberty Mut. Ins. v. Donegan*, 746 F.3d 497, 509 (2d Cir. 2014) ("Not every state law imposing a reporting requirement is preempted."). True, the Court has held that laws "compel[ling] plans to report detailed information about claims and plan members" to the state, information that overlaps with the information ERISA requires plans to report to the Secretary of Labor, have an impermissible connection with ERISA plans. *Gobeille*, 577 U.S. at 321-23. But sections 16.1(10) and 16.2(2) require only the disclosure, upon request, of basic information to pharmacies and plan sponsors; neither section requires PBMs to report to North Dakota the kind of detailed information that ERISA requires plans to report to the Secretary of Labor. *Compare* §§ 16.1(1), 16.2(2) *with Gobeille*, 577 U.S. at 321-22 (describing some of the information that ERISA plans must report to the Secretary of Labor).

The only remaining provision that PCMA claims ERISA preempts is section 16.2(3), which prohibits a PBM 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." To the extent this provision causes a drug to be unavailable to ERISA plans' North Dakota beneficiaries, "the responsibility lies first with the PBM" for refusing to satisfy the condition that would permit the drug to be available. *See Rutledge*, 141 S. Ct. at 482. Any effect that section 16.2(3) has on benefit structure is therefore attributable to the independent actions of PBMs rather than to the law and thus provides no basis for preemption. *See id.*

In sum, none of the challenged provisions has an impermissible connection with ERISA plans.

B.

A state law has an impermissible "reference to" ERISA plans if and only if it "acts immediately and exclusively upon ERISA plans" or "the existence of ERISA plans is essential to the law's operation." *Id.* at 479, 481. Previously, circuit precedent held that the existence of ERISA plans is essential to a law's operation if the law can apply to an ERISA plan. *See Pharm. Care Mgmt. Ass'n v. Gerhart*, 852 F.3d 722, 729-30 (8th Cir. 2017) (holding that the challenged law could not "function[] irrespective of . . . the existence of an ERISA plan" because it "affect[ed] ERISA plans"). In *Rutledge*, the Supreme Court clarified that the existence of ERISA plans is essential to a law's operation only if the law cannot apply to a non-ERISA plan. *See* 141 S. Ct. at 481 (explaining that "ERISA plans are . . . not essential to [the challenged law's] operation" because the law "regulates PBMs whether or not the plans they service fall within ERISA's coverage"); *accord Cal. Div. of Lab. Standards Enf't v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316, 328 (1997) (concluding that the challenged law "function[ed] irrespective of . . . the existence of an ERISA plan" because the programs it regulated did not need to fall under ERISA).

PCMA does not argue that any of the challenged provisions "refer to" ERISA plans under the standard articulated in *Rutledge*. Nor could it. The challenged provisions apply to PBMs not only insofar as they administer ERISA plans but also insofar as they administer non-ERISA plans. Therefore, they do not "act[] . . . exclusively upon ERISA plans," and ERISA plans are not "essential to [their] operation." *See Rutledge*, 141 S. Ct. at 481. Under *Rutledge*, then, none has an impermissible reference to ERISA plans. *See id.*

* * *

Because none of the challenged provisions "has a connection with or reference to" an ERISA plan, none is preempted as applied to ERISA plans. *See id.* at 479. The district court properly rejected PCMA's claims of ERISA preemption.

IV.

Unlike the scope of ERISA preemption, the scope of Medicare Part D preemption is largely an open question in this circuit. Our only case addressing the question is *Rutledge*, and for our purposes there it sufficed merely to repeat the statutory language and note that "[c]onflict between the state law and the federal standard is unnecessary" for preemption. *See* 891 F.3d at 1113. Here, our purposes require a more detailed analysis. Accordingly, we develop a framework for Medicare Part D preemption before turning to PCMA's arguments for preemption.

A.

We begin with general preemption principles. The Supremacy Clause designates federal law as "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Accordingly, a state law may not be enforced to the extent that doing so would frustrate the purpose of a federal law. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (explaining that a "state law must yield" if "the purpose

of [a federal law] cannot otherwise be accomplished—if its operation within its chosen field else must be frustrated"); *see also Hughes v. Talen Energy Mktg., LLC*, 578 U.S. ---, 136 S. Ct. 1288, 1297 (2016) ("[T]he purpose of Congress is the ultimate touchstone in every pre-emption case."). As relevant here, this occurs when a state law is inconsistent with a federal law in the sense that it is impossible to comply with both, *see PLIVA, Inc. v. Mensing*, 564 U.S. 604, 617-18, 620 (2011) (discussing "conflict" preemption), as well as when state law adds to a federal regulatory scheme that was designed to be comprehensive, *see United States v. Locke*, 529 U.S. 89, 111-12 (2000) (discussing "field" preemption). *See also Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) ("[S]tate law is pre-empted if that law actually conflicts with federal law or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it." (internal quotation marks and citations omitted)).

Normally, federal courts determine the purpose of a federal law, and thus its preemptive scope, by examining its statutory and regulatory context. *See CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993) ("Evidence of pre-emptive purpose is sought in the text and structure of the statute at issue."); *Va. Uranium, Inc. v. Warren*, 587 U.S. ---, 139 S. Ct. 1894, 1907-08 (2019) (lead opinion of Gorsuch, J.) (consulting "text and structure" to discern preemptive scope rather than "[t]rying to discern what motivate[d] legislators individually or collectively"). But when Congress explicitly declares a class of state laws preempted, we heed Congress's directive. *See Chamber of Commerce of the United States v. Whiting*, 563 U.S. 582, 594 (2011) ("When a federal law contains an express preemption clause, we 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent.'" (quoting *CSX Transp.*, 507 U.S. at 664)).

In the case of Medicare, Congress enacted an express preemption provision applicable to Medicare Part C in 42 U.S.C. § 1395w-26(b)(3) and extended it to Medicare Part D in § 1395w-112(g). Originally, § 1395w-26(b)(3) declared that federal "standards . . . shall supersede any State law or regulation . . . to the extent

such law or regulation is inconsistent with such standards." Balanced Budget Act of 1997, Pub. L. No. 105-33, § 1856(b)(3)(A), 111 Stat. 251, 319. But Congress amended § 1395w-26(b)(3) in 2003, dropping the phrase "to the extent such law or regulation is inconsistent with such standards." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 232(a), 117 Stat. 2066, 2208. Now, § 1395w-26(b)(3) declares simply that federal "standards . . . shall supersede any State law or regulation . . . with respect to [Medicare Part C] plans." Although the statute does not define the term "standard," *see* § 1395w-28, it does empower the Secretary of Health and Human Services to "establish by regulation other standards" in addition to those established by the statute itself, § 1395w-26(b)(1). Accordingly, like the district court, we conclude that a "standard" for purposes of Medicare Part D preemption "is a [Medicare Part D] statutory provision or a regulation promulgated under [Medicare Part D] and published in the Code of Federal Regulations." *Tufte*, 326 F. Supp. 3d at 888 (quoting *N.Y.C. Health & Hosps. Corp. v. WellCare of N.Y., Inc.*, 801 F. Supp. 2d 126, 140 (S.D.N.Y. 2011)); *accord Morrison v. Health Plan of Nev.*, 328 P.3d 1165, 1169 (Nev. 2014); *Trezza v. Trezza*, 957 N.Y.S.2d 380, 387 (N.Y. App. Div. 2012); *cf. Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1148 n.20 (9th Cir. 2010) (stating that, "at the narrowest cut," this is what "standard" means in § 1395w-26(b)(3)).

As amended, § 1395w-26(b)(3) "preempt[s] a broad swath of state laws." *Snyder*, 131 N.E.3d at 652. Nonetheless, it contains two limitations. First, preemption remains "with respect to [Medicare Parts C-D] plans" only, §§ 1395w-26(b)(3), 1395w-112(g), not other health-insurance plans. *See Trezza*, 957 N.Y.S.2d at 388. Second, preemption occurs only when federal standards "supersede" state law. § 1395w-26(b)(3). To "supersede" means to "displace." *Merriam-Webster's Collegiate Dictionary* 1255 (11th ed. 2005); *cf. Boyle v. United Techs. Corp.*, 487 U.S. 500, 507-08 (1988) (using "displace[d]" and "superseded" synonymously in the preemption context). Thus, § 1395w-112(g) does not preempt *all* state laws as applied to Medicare Part D; rather, it preempts only those that occupy the same "place"—that is, that regulate the same subject matter as—federal Medicare Part D standards. *See Haaland v. Presbyterian Health Plan, Inc.*, 292 F. Supp. 3d 1222,

1230 (D.N.M. 2018). In other words, the effect of the 2003 amendment was to expand the scope of express Medicare preemption from conflict preemption to field preemption. *See* Medicare Prescription Drug, Improvement, and Modernization Act § 232(a) (titling the amendment "Avoiding *duplicative* State regulation" (emphasis added)); *Snyder*, 131 N.E.3d at 652 ("[S]tate standards are preempted when they implicate 'conduct that was governed by federal Medicare standards.'" (quoting *Haaland*, 292 F. Supp. 3d at 1231)); *Morrison*, 328 P.3d at 1169 (holding that state laws are preempted "as long as a federal [Medicare] standard exists regarding the conduct at issue").

Finally, because § 1395w-26(b)(3) articulates a sufficient rather than a necessary condition for preemption, it does not exclude the possibility that a state law could frustrate the purpose of a federal Medicare Part D otherwise than by regulating the same subject matter. The Supreme Court has recognized that Congress's express designation of some state laws as preempted does not foreclose the possibility of implied preemption of other state laws. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (stating that implied preemption remained a "viable pre-emption theor[y]" even if the express preemption provision did not apply); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (applying "ordinary pre-emption principles" to laws not covered by an express preemption provision).

In sum, state laws are preempted as applied to Medicare Part D plans if and only if they either (1) regulate the same subject matter as a federal Medicare Part D standard (in which case they are expressly preempted), or (2) otherwise frustrate the purpose of a federal Medicare Part D standard (in which case they are impliedly preempted).

B.

With this framework in place, we turn to PCMA's arguments that Medicare Part D preempts the provisions at issue here. Once again, PCMA bears the burden of proving preemption. *See Williams*, 582 F.3d at 880.

1.

First, PCMA argues that 42 U.S.C. § 1395w-104(b)(1)(A) and its associated regulations establish a standard that preempts the challenged provisions to the extent that they limit the conditions that PBMs may place on pharmacies' participation in their networks. According to § 1395w-104(b)(1)(A), "[a] prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan." Federal regulations require such "terms and conditions" to be "reasonable and relevant," 42 C.F.R. § 423.505(b)(18), recognizing that they must reflect "minimum standards for pharmacy practice as established by the States," 42 C.F.R. § 423.153(c)(1).

PCMA acknowledges that 42 C.F.R. § 423.153(c)(1) authorizes states to determine which conditions a PBM *must* place on pharmacies' participation in its network. But PCMA maintains that 42 C.F.R. § 423.505(b)(18) governs which conditions a PBM *may not* place on pharmacies' participation in its network; namely, unreasonable or irrelevant conditions. Therefore, PCMA concludes, state laws that limit the conditions that PBMs may place on pharmacies' participation in their networks are preempted.

We disagree. As the district court noted, *Tufte*, 326 F. Supp. 3d at 886, the practice of pharmacy is an area traditionally left to state regulation, *see Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4194, 4278 (Jan. 28, 2005) (explaining that the Department of Health and Human Services has a "general position of deferring to States for regulating the practice of pharmacy"). We do not read 42 C.F.R. § 423.505(b)(18) as claiming this area for federal control pursuant to Medicare

Part D's express preemption provision. On the contrary, the highly general language of the regulation—requiring only that plans "have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may . . . participate as a network pharmacy," *see* 42 C.F.R. § 423.505(b)(18)—indicates an intent to leave to the states the specifics of what plans and PBMs may or may not demand of pharmacies. *Cf. Contract Year 2019 Policy and Technical Changes to Medicare Programs*, 83 Fed. Reg. 13440, 16598 (Apr. 16, 2018) (indicating that the Center for Medicare and Medicaid Services ("CMS") does not consider the provisions at issue here to be problematic).

2.

PCMA's second argument is based on 42 U.S.C. § 1395w-111(i), which provides that the Secretary of Health and Human Services ("HHS") "(1) may not interfere with the negotiations between drug manufacturers and pharmacies and [sponsors of prescription-drug plans]; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." Because none of the challenged provisions purports to regulate what the HHS Secretary may do, § 1395w-111(i) does not displace any of the challenged provisions under Medicare Part D's express preemption provision. That said, it is plausible that state laws doing what § 1395w-111(i) prohibits the HHS Secretary from doing would frustrate § 1395w-111(i)'s express purpose "to promote competition." Accordingly, we held in *Rutledge* that paragraph (1) of § 1395w-111(i) "prohibits both federal and state interference in negotiations between Part D sponsors and pharmacies," 891 F.3d at 1113, and PCMA urges us to hold the same with respect to paragraph (2). For our purposes, it suffices to assume without deciding that PCMA is correct—that is, that paragraph (2) impliedly preempts state laws that "require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."

Starting with 42 U.S.C. § 1395w-111(i)(1), PCMA argues that "many" of the challenged provisions interfere with negotiations between pharmacies and PBMs by

limiting the terms and conditions that PBMs can bargain for when contracting with pharmacies. As the defendants point out, this argument proves too much. It implies that the Secretary of Health and Human Services may not regulate contracts between plans and pharmacies at all, *but see* 42 C.F.R. § 423.505(b)(18), and neither may the states, *but see* 42 C.F.R. § 423.153(c)(1).

A better interpretation of 42 U.S.C. § 1395w-111(i)(1) would limit the "negotiations" that it protects from interference to negotiations about which drugs the pharmacy must carry and what prices the pharmacy may charge for them. In addition to squaring with 42 C.F.R. §§ 423.153(c)(1) and .505(b)(18), this interpretation fits more comfortably with the statutory context: the provision immediately following § 1395w-111(i)(1) prohibits the Secretary from "requir[ing] a particular formulary or institut[ing] a price structure." *See* 42 U.S.C. § 1395w-111(i)(2).

None of the challenged provisions interferes with negotiations between PBMs and pharmacies regarding formularies or prices. True, section 16.2(5) prohibits a PBM from prohibiting a pharmacy from dispensing drugs allowed under its license, thereby preventing the PBM from insisting on a list of drugs that the pharmacy *may not* dispense. But section 16.2(5) does not prevent the PBM from insisting on a list of drugs that the pharmacy *must* dispense. And although section 16.1(3) prohibits a PBM from charging a pharmacy certain fees, these fees do not relate to the prices of drugs.

Turning to 42 U.S.C. § 1395w-111(i)(2), PCMA claims that some of the challenged provisions "require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." This is false. As the district court observed, the challenged provisions have "no bearing on whether a drug may be listed on a formulary, and [they] contain[] no language banning formularies or compelling Part D plans to cover any drugs." *See Tufte*, 326 F. Supp. 3d at 890-91.

In sum, none of the challenged provisions (1) "interfere[s] with the negotiations between" pharmacies and PBMs regarding what drugs the pharmacy must carry and what prices the pharmacy may charge for them, 42 U.S.C. § 1395w-111(i)(1), or (2) "require[s] a particular formulary or institute[s] a price structure for the reimbursement of covered part D drugs," 42 U.S.C. § 1395w-111(i)(2). Therefore, 42 U.S.C. § 1395w-111(i) does not impliedly preempt any of the challenged provisions.

3.

Finally, PCMA cites miscellaneous federal Medicare Part D standards, each of which it claims preempts a subset of the challenged provisions. We agree with PCMA on some but not all of its claims.

First, PCMA argues that federal standards regulating formularies, *see, e.g.*, 42 C.F.R. § 423.120(b), preempt section 16.2(5), which prohibits a PBM from prohibiting a pharmacy from "dispens[ing] any and all drugs allowed under [its] license." But a "formulary" is simply the "list of Part D drugs covered by a Part D plan," 42 C.F.R. § 423.4, and authorizing pharmacies to dispense all drugs allowed under their licenses does not constitute regulating which drugs a Medicare Part D plan must cover. Therefore, federal standards regulating formularies do not displace section 16.2(5) under Medicare Part D's express preemption provision. And PCMA has offered no reason to conclude that these standards impliedly preempt section 16.2(5), either.

Second, PCMA argues that sections 16.1(8)-(9), which prohibit PBMs from prohibiting pharmacies from mailing drugs and charging a shipping-and-handling fee, are preempted for two reasons: (1) because CMS has "determined that specialty pharmacies must be able to mail prescriptions," and (2) because CMS already regulates "delivery" costs. In support of its first reason, PCMA directs our attention to a notice-and-comment exchange in which CMS expressed concern about "contracting terms and conditions that explicitly prohibited pharmacies in retail

networks from mailing any prescriptions, with network termination as the consequence." *See Contract Year 2019 Policy and Technical Changes to Medicare Programs*, 83 Fed. Reg. at 16595. PCMA fails to explain why this shows that sections 16.1(8)-(9), which prohibit exactly what CMS appears to have found concerning, conflict with, regulate the same subject matter as, or otherwise frustrate the purpose of any federal Medicare Part D standard. In support of its second reason, PCMA merely cites to the statutory definition of "dispensing fees," which refers to "delivery" costs. *See* 42 C.F.R. § 423.100. Again, PCMA fails to explain how this shows that sections 16.1(8)-(9) are expressly or impliedly preempted by any federal Medicare Part D standard.

Third, PCMA cites federal standards requiring plans to disclose certain information to patients, *see* 42 U.S.C. § 1395w-104(a)(1), or prohibiting plans from prohibiting pharmacies from disclosing certain information to patients, *see* 42 U.S.C. § 1395w-104(m). According to PCMA, these standards preempt section 16.1(7) and the challenged portions of 16.1(5), both of which prohibit PBMs from prohibiting pharmacies from disclosing certain information to patients. The defendants concede, and we agree, that 42 U.S.C. § 1395w-104(m) regulates the same subject matter as and therefore displaces section 16.1(7) and the challenged portions of section 16.1(5) under Medicare Part D's express preemption provision.

Fourth, PCMA argues that federal standards requiring PBMs to disclose certain information to federal agencies, *see, e.g.*, 42 C.F.R. § 423.514(d), preempt section 16.1(10), which requires PBMs to disclose certain basic information to pharmacies upon request. As the district court pointed out, however, disclosures to federal agencies constitute a distinct subject matter from disclosures to pharmacies. *See Tufte*, 326 F. Supp. 3d at 896; *cf. Lawson-Ross v. Great Lakes Higher Educ. Corp.*, 955 F.3d 908, 917 (11th Cir. 2020) (holding that 20 U.S.C. § 1098g's express preemption of state "disclosure requirements" extends only to "the type of disclosures to borrowers that [20 U.S.C.] § 1083 requires"). Therefore, federal standards such as 42 C.F.R. § 423.514(d) do not displace section 16.1(10) under

Medicare Part D's express preemption provision. And PCMA has offered no reason to conclude that these standards impliedly preempt section 16.1(10), either.

Fifth, PCMA cites federal standards requiring plan sponsors to "have in place" a "cost-effective drug utilization management program, including incentives to reduce costs," as well as "[q]uality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use." *See* 42 U.S.C. § 1395w-104(c)(1)(A)-(B). According to PCMA, these standards preempt section 16.1(3), which requires PBMs to "utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures" and limits the performance-based fees that PBMs can charge pharmacies. We agree. Although section 16.1(3) does not conflict with 42 U.S.C. § 1395w-104(c)(1)(A)-(B), it does regulate the same subject matter; namely, quality-assurance measures and performance incentives. *Cf. Morrison*, 328 P.3d at 1169-70 (holding that Medicare Part C standards regarding, *inter alia*, "quality improvement programs" regulate the same conduct as and thus preempt state "quality assurance" requirements). Therefore, 42 U.S.C. § 1395w-104(c)(1)(A)-(B) displaces section 16.1(3) under Medicare Part D's express preemption provision.

Sixth, PCMA reiterates its argument that 42 U.S.C. § 1395w-104(b)(1)(A) preempts sections 16.1(11) and 16.2(4). This argument fails for the reasons explained in Section IV.B.1, *supra*.

Seventh, PCMA argues that federal standards governing the collection of retroactive fees from pharmacies, *e.g.*, 42 C.F.R. § 423.464(f)(6), preempt section 16.1(2), which provides:

> A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:
>
> a. That is not apparent at the time of claim processing;

b. That is not reported on the remittance advice of an adjudicated claim; or

c. After the initial claim is adjudicated at the point of sale.

The defendants concede that section 16.1(2)(c) is preempted because it prohibits retroactive fees. But they maintain that sections 16.1(2)(a)-(b) are not preempted because they concern only the disclosure of fees, not the timing of fees. We disagree. The defendants fail to explain how the retroactive fees contemplated by federal regulations will typically be "apparent at the time of claim processing" and available to be "reported on the remittance advice of an adjudicated claim." *See* § 16.1(2); *cf.* 42 C.F.R. § 423.100 (contemplating the imposition of fees that "cannot reasonably be determined at the point-of-sale"). Because they encroach on territory covered by federal standards, not only section 16.1(2)(c) but also sections 16.1(2)(a)-(b) are preempted under Medicare Part D's express preemption provision.

Eighth, PCMA argues that federal regulations regarding copayments, *see, e.g.*, 42 C.F.R. § 423.104(d)(2)(i)-(ii) (regulating copayment amounts), preempt the challenged portions of section 16.1(4), which prevent PBMs from clawing back copayments from pharmacies. As the district court noted, however, PCMA has not identified a federal standard that governs who is entitled to keep a copayment. *See Tufte*, 326 F. Supp. 3d at 895. Therefore, PCMA has failed to show that the challenged portions of section 16.1(4) fall within the scope of Medicare Part D's express preemption provision. Nor has PCMA offered any reason to conclude that the challenged portions of section 16.1(4) are impliedly preempted.

Ninth, PCMA suggests in passing that section 16.2(3), which addresses certain conflicts of interest that PBMs might have, is preempted because some federal regulations also address potential conflicts of interest, *see, e.g.*, 42 C.F.R. § 423.504(b)(4)(vi)(G). Because the regulations that PCMA cites address different kinds of conflicts of interest, they do not displace section 16.2(3) under Medicare

Part D's express preemption provision. And PCMA has offered no reason to conclude that the regulations that it cites impliedly preempt section 16.2(3), either.

V.

For the foregoing reasons, we affirm the district court's judgment that none of the challenged provisions is preempted as applied to ERISA plans; we affirm the district court's judgment that section 16.2(2) is preempted as applied to Medicare Part D plans; we reverse the district court's judgment that section 16.1(2), section 16.1(3), the challenged portions of section 16.1(5), and section 16.1(7) are not preempted as applied to Medicare Part D plans; and we affirm the district court's judgment that sections 16.1(8), 16.1(9), 16.1(10), 16.1(11), 16.2(3), 16.2(4), and 16.2(5), as well as the challenged portions of section 16.1(4), are not preempted as applied to Medicare Part D plans.

Agenda Item #2

Hear from States on Implementation of Pharmacy Benefit Manager (PBM) Laws —TK Keen (OR)

A. ***Connecticut—Paul Lombardo (CT)***
B. ***Oklahoma—Kelli Price (OK)***
C. ***Virginia—Don Beatty (VA)***
D. ***Wisconsin—Nathan Houdek (WI)***

OKLAHOMA INSURANCE DEPARTMENT

PHARMACY BENEFITS MANAGERS, LEGAL COMPLIANCE & ENFORCEMENT

Kelli Price

Managing Counsel / Director of PBM Compliance and Enforcement Division

December 11, 2021

INSURANCE COMMISSIONER STATE OF OKLAHOMA

Patient's Right to Pharmacy Choice Act, Title 36 O.S. §§ 6958-6968. Effective Nov. 1, 2019

Oklahoma's Pharmacy Choice Act "establish[es] minimum and uniform access to a provider and standards and prohibitions on restrictions of a patient's right to choose a pharmacy provider," such as:

- Urban, suburban, and rural geographical requirements for pharmacy access;
- Prohibits PBMs and benefit plans from requiring patients to use pharmacies that are directly or indirectly owned by the PBM or benefit plans;
- Requires PBMs and plans to list all pharmacies and providers on promotional materials, if any are listed;
- Bars PBMs or plans from charging pharmacies certain fees (for submission of a claim, etc.);
- Bars PBMs from reimbursing independent pharmacies at a lesser amount than PBM-owned pharmacies;
- Bars PBMs from denying a pharmacy opportunity to participate in a pharmacy network if it is willing to follow the same rules as everyone else. (ANY WILLING PROVIDER)
- Prohibits incentives related to mail-order, cost-sharing, co-pays, or other discounts

Rutledge Decision (141 S. Ct. 474) and Impact on Oklahoma PBM Regulation

In December, 2020, the U.S. Supreme Court decided the *Rutledge v. PCMA* case out of Arkansas and the 10th Circuit.

At issue: Arkansas statute ("Act 900") that required PBMs to tether their reimbursement rates to the acquisition costs pharmacies pay, by updating price schedules whenever wholesale drug prices increase.

- Employee Retirement Income Security Act (ERISA) preempts "any and all state laws" that "relate to any employee benefit plan."

Court ruling: "ERISA does not pre-empt state rate regulations that merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage."

- No Preemption of:
  - ✓ Health care cost regulation
  - ✓ Health plan intermediaries
  - ✓ Issues not covered by ERISA regs

Enjoined from enforcement…

- On October 25, 2019 (6 days before it was scheduled to take effect), Pharmaceutical Care Management Association (PCMA), a trade association of PBMs, sued to enjoin enforcement of the Patient's Right to Pharmacy Choice Act. *PCMA v. Glen Mulready and Oklahoma Insurance Department* (CIV-19-77-J) is still currently pending final resolution in the United States District Court for the Western District of Oklahoma.

- Initially, the litigation prevented OID from moving forward with enforcement of the Patient's Right to Pharmacy Choice Act. On July 9, 2020, federal district court for the Western District of Oklahoma ruled the Commissioner could proceed with enforcement of the majority of the provisions of the Act. PCMA appealed that ruling to the 10th Circuit Court of Appeals in Denver and filed an emergency motion to stay enforcement of the Act. The 10th Circuit denied PCMA's emergency motion.

- As of September 1, 2020, the Commissioner was able to proceed with enforcement of the Act (with the exception of regulating promotional materials & network access when related to Medicare plans).

PBMs & Enforcement:
Setting Your Team Up for Success!

OID created a division focused solely on PBM compliance & enforcement, hiring staff with applicable knowledge and expertise including:

- An industry expert/pharmacist consultant
  - From the beginning, OID hired an industry expert who had retired recently as a pharmacist. Previously, he had owned his own pharmacy, worked for other pharmacies, he was an auditor for a PBM, and was Director of Pharmacy at 2 health insurance companies. His industry expertise has been invaluable to OID, particularly his ability to explain the interests and processes of the various industry stakeholders and how they interact and conflict with each other.
- 3 PBM Compliance & Enforcement agents (who have prior insurance related and/or investigation experience)
- 2 Attorneys with insurance, medical and/or legislative experience

PBMs & Enforcement:
Setting Your Team Up for Success! (Cont'd)

- Through its website, OID created a process for customers to submit their complaints against PBMs on-line.
  - As a customer fills in their answers, the software is prompted to ask more specific questions based on the type of complaint and the specific violations alleged.
  - The questions are tailored in order to allow OID to gather, from the beginning, as much information and evidence as possible. This allows OID to save time, minimize unnecessary correspondence and response time, and more quickly determine what, if any, violation exists and if enough evidence exists to prove the elements of a particular violation.
  - Complaints and accompanying evidence are then routed to the PBM Compliance and Enforcement Division's email address where the OID Agent reviews it and begins their investigation.

PBMs & Enforcement:
Setting Your Team Up for Success! (Cont'd)

- Develop Standard Correspondence and Forms:
  - ✓ The PBM Compliance & Enforcement Division developed templates for typical correspondences sent to PBMs and complainants.
  - ✓ The Division also developed a "Blue Sheet" specific to PBM violations of Oklahoma regulations which OID agents use to succinctly summarize their investigations and more quickly refer their cases to legal for enforcement actions.

- OID's PBM legal team developed a standard "Invitation to Settle" letter which has helped facilitate conversation, leading to quick and amicable resolutions, rather than necessitating litigation.

PBMs & Enforcement:
Challenges, Lessons Learned & Success

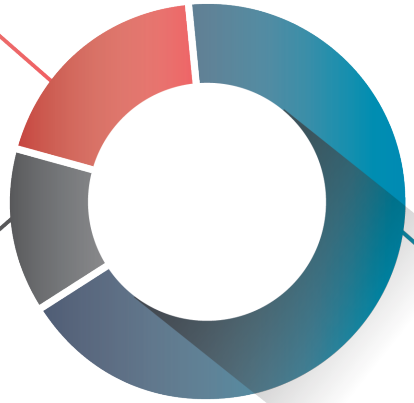
- The language of legislation can open or close loopholes.
  - ✓ Check with a regulating attorney – Can the intent of the language actually be *enforced* legally?
  - ✓ Grammar and the structure of paragraphs matter!
  - ✓ Using specific terms can create loopholes unintentionally. For example: "specialty pharmacy" or "specialty drugs." When possible, keep it general.
- Lack of Communication between a PBM and a pharmacy (or PSAO) is often the culprit that leads to contention.
  - ✓ Check to see if the parties have actually tried to communicate with each other.
  - ✓ Check to see if a technology issue has led to a break-down in communication (ex. Software isn't speaking the same language).

PBMs & Enforcement:
Challenges, Lessons Learned & Success

- Ask for the specific information you *really* need, so you don't end up with reams of documents that you will have to sort and filter through…
  - ✓ What elements are needed to prove a violation of statute?
  - ✓ Ask the complainant and/or the PBM for information and documentation related to each element necessary to prove a violation.
  - ✓ If you ask for a large document, ask the complainant or PBM to reference the specific information within the document you are really looking for.
- Communication with all stakeholders is key!
  - ✓ Contention in the industry has led to mistrust all-around. Having in-depth conversations and explaining *WHY* we need specific information, documents, or language in legislation has been a huge help in building trust and cooperation with all sides.
  - ✓ Building relationships has led to quicker and more amicable resolutions and helped to bring clarity and close loopholes in legislation.

OKLAHOMA INSURANCE DEPARTMENT

135,072 Alleged Violations of PBMs received and reviewed since 9/1/2020, including:



25,974
alleged violations from Sept. 2020 through June 2021

91,337
alleged violations from July 2021 through Sept. 2021

17,761
alleged violations from Oct. 2021 through Nov. 2021

INSURANCE COMMISSIONER STATE OF OKLAHOMA

OKLAHOMA INSURANCE DEPARTMENT

Kelli Price
Managing Counsel /
Director of PBM Compliance & Enforcement Division
400 NE 50th Street
Oklahoma City, OK 73105
405-522-6350
Kelli.Price@oid.ok.gov

VIRGINIA

Chapter 34. Provisions Relating to Accident and Sickness Insurance » Article 9. Pharmacy Benefits Managers

Article 9. Pharmacy Benefits Managers.

§ 38.2-3465. (Effective October 1, 2020) Definitions.

A. As used in this article, unless the context requires a different meaning:

"Carrier" has the same meaning ascribed thereto in subsection A of § 38.2-3407.15. However, "carrier" does not include a nonprofit health maintenance organization that operates as a group model whose internal pharmacy operation exclusively serves the members or patients of the nonprofit health maintenance organization.

"Claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of administering, filling, or refilling a prescription for a drug or for providing a medical supply or device.

"Claims processing services" means the administrative services performed in connection with the processing and adjudicating of claims relating to pharmacist services that include (i) receiving payments for pharmacist services, (ii) making payments to pharmacists or pharmacies for pharmacist services, or (iii) both receiving and making payments.

"Covered individual" means an individual receiving prescription medication coverage or reimbursement provided by a pharmacy benefits manager or a carrier under a health benefit plan.

"Health benefit plan" has the same meaning ascribed thereto in § 38.2-3438.

"Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail or through electronic submissions and to dispense medication to covered individuals through the use of the United States mail or other common or contract carrier services and that provides any consultation with covered individuals electronically rather than face-to-face.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of covered individuals. "Pharmacy benefits management" does not include any service provided by a nonprofit health maintenance organization that operates as a group model provided that the service is furnished through the internal pharmacy operation exclusively serves the members or patients of the nonprofit health maintenance organization.

"Pharmacy benefits manager" or "PBM" means an entity that performs pharmacy benefits management. "Pharmacy benefits manager" includes an entity acting for a PBM in a contractual relationship in the performance

of pharmacy benefits management for a carrier, nonprofit hospital, or third-party payor under a health program administered by the Commonwealth.

"Pharmacy benefits manager affiliate" means a business, pharmacy, or pharmacist that directly or indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership interest or control with a pharmacy benefits manager.

"Rebate" means a discount or other price concession, including without limitation incentives, disbursements, and reasonable estimates of a volume-based discount, or a payment that is (i) based on utilization of a prescription drug and (ii) paid by a manufacturer or third party, directly or indirectly, to a pharmacy benefits manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

"Retail community pharmacy" means a pharmacy that is open to the public, serves walk-in customers, and makes available face-to-face consultations between licensed pharmacists and persons to whom medications are dispensed.

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a health benefit plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

2020, cc. 219, 1288.

§ 38.2-3466. (Effective October 1, 2020) License required to provide pharmacy benefits management services; requirements for a license, renewal, and revocation or suspension.

A. Unless otherwise covered by a license as a carrier, no person shall provide pharmacy benefits management services or otherwise act as a pharmacy benefits manager in the Commonwealth without first obtaining a license in a manner and in a form prescribed by the Commission.

B. Each applicant for a license as a pharmacy benefits manager shall make application to the Commission, in the form and containing the information listed in subsection C and any other information the Commission prescribes. The Commission may require any documents reasonably necessary to verify the information contained in an application. Each applicant shall, at the time of applying for a license, pay a nonrefundable application processing fee in an amount and in a manner prescribed by the Commission. The fee shall be collected by the Commission and paid directly into the state treasury and credited to the "Bureau of Insurance Special Fund — State Corporation Commission" for the maintenance of the Bureau of Insurance as provided in subsection B of § 38.2-400.

C. An applicant for a license as a pharmacy benefits manager shall provide the Commission the following information:

1. The name, address, and telephone contact number of the pharmacy benefits manager;

2. The name and address of each person with management or control over the pharmacy benefits manager;

3. The name and address of each person with a beneficial ownership interest in the pharmacy benefits manager; and

4. If the pharmacy benefits manager registrant (i) is a partnership or other unincorporated association, a limited liability company, or a corporation and (ii) has five or more partners, members, or stockholders, the registrant shall specify its legal structure and the total number of its partners, members, or stockholders who, directly or indirectly, own, control, hold with the power to vote, or hold proxies representing 10 percent or more of the voting securities of any other person.

D. An applicant shall provide the Commissioner with a signed statement indicating that, to the best of its knowledge, no officer with management or control of the pharmacy benefits manager has been convicted of a felony or has violated any of the requirements of state law applicable to pharmacy benefits managers, or, if the applicant cannot provide such a statement, a signed statement describing the relevant conviction or violation.

E. Except where prohibited by state or federal law, by submitting an application for a license, the applicant shall be deemed to have appointed the clerk of the Commission as the agent for service of process on the applicant in any action or proceeding arising in the Commonwealth out of or in connection with the exercise of the license. Such appointment of the clerk of the Commission as agent for service of process shall be irrevocable during the period within which a cause of action against the applicant may arise out of transactions with respect to subjects of pharmacy benefits management in the Commonwealth. Service of process on the clerk of the Commission shall conform to the provisions of Chapter 8 (§ 38.2-800 et seq.).

F. Each applicant that has complied with the provisions of this article and Commission regulations is entitled to and shall receive a license in the form the Commission prescribes.

G. Each pharmacy benefits manager shall renew its license annually and shall, at the time of renewal, pay a renewal fee in an amount and in a manner prescribed by the Commission. The fee shall be collected by the Commission and paid directly into the state treasury and credited to the "Bureau of Insurance Special Fund — State Corporation Commission" for the maintenance of the Bureau of Insurance as provided in subsection B of § 38.2-400.

H. The Commission may refuse to issue or renew a license or may revoke or suspend a license if it finds that the applicant or license holder has not complied with the provisions of this article or Commission regulations.

2020, cc. 219, 1288.

§ 38.2-3467. (Effective October 1, 2020) Prohibited conduct by carriers and pharmacy benefits managers.

A. No carrier on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager shall:

1. Cause or knowingly permit the use of any advertisement, promotion, solicitation, representation, proposal, or offer that is untrue;

2. Charge a pharmacist or pharmacy a fee related to the adjudication of a claim other than a reasonable fee for an initial claim submission;

3. Reimburse a pharmacy or pharmacist an amount less than the amount that the pharmacy benefits manager reimburses a pharmacy benefits manager affiliate for providing the same pharmacist services, calculated on a per-unit basis using the same generic product identifier or generic code number and reflecting all drug manufacturer's rebates, direct and indirect administrative fees, and costs and any remuneration; or

4. Penalize or retaliate against a pharmacist or pharmacy for exercising rights provided pursuant to the provisions of this article.

B. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall restrict participation of a pharmacy in a pharmacy network for provider accreditation standards or certification requirements if a pharmacist meets such accreditation standards or certification standards.

C. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall include any mail order pharmacy or pharmacy benefits manager affiliate in calculating or determining network adequacy under any law or contract in the Commonwealth.

D. No carrier, on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager, shall conduct spread pricing in the Commonwealth.

E. Each carrier on its own or through its contracted pharmacy benefits manager or representative of a pharmacy benefits manager shall comply with the provisions of this section in addition to complying with the provisions of § 38.2-3407.15:1.

2020, cc. 219, 1288.

§ 38.2-3468. (Effective October 1, 2020) Examination of books and records; reports; access to records.

A. Each carrier, on its own or through its contract for pharmacy benefits, shall ensure that the Commissioner may examine or audit the books and records of a pharmacy benefits manager providing claims processing services or other prescription drug or device services for a carrier that are relevant to determining if the pharmacy benefits manager is in compliance with this article. The carrier shall be responsible for the charges incurred in the examination, including the expenses of the Commissioner or his designee and the expenses and compensation of his examiners and assistants.

B. Any carrier, on its own or through its contract for pharmacy benefits, shall report to the Commissioner on a quarterly basis for each health benefit plan the following information:

1. The aggregate amount of rebates received by the pharmacy benefits manager;

2. The aggregate amount of rebates distributed to the appropriate health benefit plan;

3. The aggregate amount of rebates passed on to the enrollees of each health benefit plan at the point of sale that reduced the enrollees' applicable deductible, copayment, coinsurance, or other cost-sharing amount;

4. Upon the request of the Commission, the individual and aggregate amount paid by the health benefit plan to the pharmacy benefits manager for services itemized by pharmacy, by product, and by goods and services; and

5. Upon the request of the Commission, the individual and aggregate amount a pharmacy benefits manager paid for services itemized by pharmacy, by product, and by goods and services.

C. All working papers, documents, reports, and copies thereof, produced by, obtained by or disclosed to the Commission or any other person in the course of an examination made under this article and any analysis of such information or documents shall be given confidential treatment, are not subject to subpoena, and may not be made public by the Commission or any other person. Access may also be granted to (i) a regulatory official of any state or country; (ii) the National Association of Insurance Commissioners (NAIC), its affiliate, or its subsidiary; or (iii) a law-enforcement authority of any state or country, provided that those officials are required under their law to maintain its confidentiality. Any such disclosure by the Commission shall not constitute a waiver of confidentiality of such papers, documents, reports or copies thereof. Any parties receiving such papers must agree in writing prior to receiving the information to provide to it the same confidential treatment as required by this section.

2020, cc. 219, 1288.

§ 38.2-3469. (Effective October 1, 2020) Enforcement; regulations.

A. The Commission shall enforce this article.

B. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and regulations as it may deem necessary to implement this article.

2020, cc. 219, 1288.

§ 38.2-3470. (Effective October 1, 2020) Scope of article.

This article shall not apply with respect to claims under (i) an employee welfare benefit plan as defined in section 3 (1) of the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1002(1), that is self-insured or self-funded; (ii) coverages issued pursuant to Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid); or (iii) prescription drug coverages issued pursuant to Part D of Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare Part D).

2020, cc. 219, 1288.

Wisconsin Office of the
COMMISSIONER
OF INSURANCE

Prescription Drug Affordability Efforts and PBM Law

Deputy Commissioner Nathan Houdek

Governor's Task Force on Reducing Prescription Drug Prices

Task Force created by Executive Order in August 2019 and charged with developing recommendations to reduce the price of prescription drugs

21 Members

- OCI Deputy Commissioner Chair
- Broad representation across Task Force members
  - State agencies (Departments of Health, Justice, and Consumer Protection), state legislators, insurers, physicians, hospitals, pharmacists, pharmaceutical manufacturers, pharmacy benefit manager (PBM), free and charitable clinics, consumer advocates

Governor's Task Force on Reducing Prescription Drug Prices

- Held 8 public meetings from Nov 2019 to August 2020
- Heard presentations from 24 organizations largely representing a mix of supply chain entities and consumers
- In October 2020, released a report proposing over 20 policy solutions centered on:
  - Lowering prices and controlling costs
  - Increasing transparency and consumer protection
  - Access for vulnerable populations

Task Force Recommendations: Lower Prices & Control Costs

- Prescription Drug Affordability Review Board
- Prescription Drug Importation Program
- State Prescription Drug Purchasing Entity
- Wisconsin Drug Repository Program enhancements
- Prohibit co-pay accumulators for drug discounts
- Real-time patient pharmacy benefit tool

Task Force Recommendations: Increase Transparency & Protect Consumers

- Office of Prescription Drug Affordability (16 new staff)
- Require transparency and reporting across the Rx drug supply chain
- Increase oversight and require licensure of PBMs, PSAOs, PBM brokers, and pharmaceutical sales reps
- Require hospital reporting for 340B program participants
- Require PBM fiduciary duty to plan sponsors
- Protections against deceptive marketing and advertising practices

Task Force Recommendations: Access for Wisconsin's Most Vulnerable

- $50 co-pay cap for insulin
- Insulin Safety Net Program
- Prohibit discriminatory reimbursement in 340B program
- $4M funding increase for free & charitable clinics
- Allow pharmacists to earn 10 hours CE for volunteering at free & charitable clinics

Governor’s Executive Budget

- Governor Evers included the Task Force recommendations in his 2021-2023 biennial budget
- PBM provisions were included in the Governor’s budget and introduced as separate, bipartisan legislation
- All Rx provisions were removed during the budget process
- Introduced as separate, stand-alone bills and packaged as “Less for Rx”

PBM Law - Process

- Bi-partisan PBM bill initially introduced in 2019-21 legislative session
- An amended version of the bill was passed by the Assembly 11 months after first being introduced
  - Failed to pass in the Senate due to the COVID-19 pandemic
- Reintroduced at the beginning of the 2021-23 legislative session
- PBM law enacted in March 2021 – (2021 Wisconsin Act 9)

PBM Law – Key Provisions

- Gag clauses prohibited *(March 2021)*
- Several requirements for insurers/PBMs conducting an audit of a pharmacy/pharmacist *(June 2021)*
- Annual PBM rebate report *(June 2021)*
  - Aggregate rebate amount the PBM received from all pharmaceutical manufacturers but retained and did not pass through to insurers
  - Must include the percentage of aggregate rebate amount that is retained
  - Reports are trade secret
  - Commissioner cannot expand upon the reporting requirement
- PBM licensure required *(January 2022)*
  - Initial fee and renewal fee is $100

PBM Law – Key Provisions

- Insurer/PBM 30-day consumer notice of formulary change or change in benefit tier *(January 2022)*
- Pharmacy notice to consumer if a drug is removed from the formulary and the insurer/PBM adds a generic drug as an alternative *(January 2022)*
  - If enrollee has an adverse reaction to the generic alternative, pharmacist may extend the originally prescribed drug for one 30-day supply
- PBMs must provide a pharmacy with certification or accreditation requirements within 30 days of a written request from a pharmacy *(January 2022)*
  - PBMs cannot change their requirements more than once every 12 months
- Limitations on a PBMs ability to retroactively deny or reduce a pharmacy's claim after adjudication *(January 2022)*

Next Steps

- Continue building support to advance the other Task Force recommendations
- Learn from efforts of other states that are enacting prescription drug oversight laws
- Encourage action by the federal government

Questions?

To learn more about the Governor's Task Force on Reducing Prescription Drug Prices, visit: RxDrugTaskForce.wi.gov

Agenda Item #3

Discuss Work Plan for Completing White Paper—*TK Keen (OR)*

Agenda Item #4

Discuss Any Other Matters Brought Before the Subgroup—TK Keen (OR)