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PREEMPTION STANDARDS AND APPLICATIONS

Part D Preemption	If state law purports to either (1) regulate the same subject matters as a Part D "standard," or (2) frustrate the purpose of a Part D standard, it is preempted. Part D "standards" are defined in Wehbi as either (1) Medicare Part D statutory provision OR (2) a regulation promulgated under Part D and published in the CFR.
ERISA preempts "any and all State laws insofar as they may now or hereafter <u>relate to</u> any employee benefit plan" covered by ERISA. 29 U.S.C. 1144(a). A state law <u>relates to</u> an ERISA plan if it has a <u>connection</u> with or <u>reference to such a plan</u> . <i>Rutledge v. Pharm. Care Mgmt. Ass'n</i> , 141 S. Ct. 474 (2020).	
ERISA "Reference to" Application	A state law has an impermissible reference to a ERISA plans if and only if it acts immediately and exclusively upon ERISA plans or is essential to the law's operations.
ERISA "Connection with" Application	A state law has an impermissible connection with ERISA if it governs a central matter of plan administration; it interferes with nationally uniform plan administration; or indirect economic effects of the law require adoptment of substantive coverage or restrict choice.
<i>Rutledge</i> Interpretation	"The mechanisms that PCMA identifies"—the appeal, update, and decline-to-dispense provisions—"do not require plan administrators to structure their benefit plans in any particular manner." 141 S. Ct. at 482. "True," the Court continued, PBMs must comply with State law in their interactions with pharmacies, but the same could be said about any State law regulating a plan's interactions with the provider of "a medical benefit." <i>Id. Along the way, the Supreme Court emphasized that ERISA is concerned primarily with State laws that "requir[e] payment of specific benefits" or "bind[] plan administrators to specific rules for determining beneficiary status." <i>Id. at 480.</i></i>

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CASE	ERISA	TYPE OF PREEMPTION ANALYSIS	CITATION	OK PATIENT RIGHT TO PHARMACY LAW ACT PROVISION OR N.D.	CITATION	PREEMPTED?	COURT'S REASONING	STATE CONCEDED PREEMPTION
Mulready	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Retail-Only Pharmacy Access Standards	Okla. Stat. 36, 6961(A), (B)	No	The OK law does not prohibit the use of mail order pharmacies; the use of the pharmacies just does not count toward meeting access standards & the plan cannot restrict an individual's choice of in-network pharmacy	
Mulready	ERISA	"Connection with" standard	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Any Willing Provider provision	Okla. Stat. 36, 6962(B) (4)	No	The OK AWP applies only to preferred network participation status of pharmacies already in the plan; it does not require a plan to accept any pharmacy into its plan	
Mulready	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Affiliated Pharmacy Prohibition and Network Provider Restriction	Okla. Stat. 36, 6961(C)	No	The OK law does not prohibit including affiliated pharmacies in the plan network; the plan is just prohibited from requiring patients to use affiliated pharmacies	
Mulready	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Probation-Based Pharmacy Limitation Prohibition and Termination Payment Requirement	Okla. Stat. 36, 6962(B) (5), (7)	No	The OK law addresses a pharmacy's contract, not the contract with the plan	
Mulready	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Network Provider Restriction	Okla. Stat. 36, 6963(E)	No	The OK law relates to pharmacies that are in network providers, and leaves the plan with many option as to the composition of in network providers	
Mulready	ERISA	"Connection with" Application	Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020)	Promotional Materials Provision	Okla. Stat. 36, 6961(D)	No	The OK law does not regulate benefit design disclosures; it only regulates how PBMs can advertise its providers	
Mulready	ERISA	"Connection with" Application	Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020)	Post-Sale Price Reduction Prohibition; Affiliated Pharmacy Price Match	Okla. Stat. 36, 6962(B) (6); Okla. Stat. 36, 6962(B)(3)	No	These provisions do not impermissibly dictate the design of an ERISA plan because they do not force the plans to make a specific choice (but court acknowledged that these provisions may have some effect on how PBMs pay or reimburse pharmacies)	
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Wehbi	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Disclosure of information; provide information to a patient; mail or deliver drugs to a patient as an ancillary service; charge shipping/ handling fees	N.D. 16.1(5), (7), (8), and (9)	No	These regulations constitute non-central plan administration with de minimus economic effects and no impact on uniformity of plan administration across states	
Wehbi	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Limits placed on the accreditation requirements that a PBM may impose on a pharmacy for network participation	N.D. 16.1(11); 16.2(4)	No	While there may be a risk of disuniformity in plan administration, these provisions do not requirement payment of specific benefits or bind plan administrators to specific rules	
Wehbi	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Mandated disclosure of information to pharmacies and plans	N.D. 16.1(10); 16.2(2)	No	Detailed disclosure obligations overlap with ERISA requirements, but the disclosure of basic information upon request does not conflict with ERISA's requirements	
Wehbi	ERISA	"Connection with" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	Prohibition on PBMs having an ownership interest in a patient assistance program or mail order pharmacy (unless the PBM agrees not to participate in the beneficial transaction)	N.D. 16.2(3)	No	The potential impact that this regulation has on the drug availability (structure of the plan) is only due to the PBM refusing to satisfy the condition that permits a drug to be available	

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Rutledge	ERISA	"Connection with" Application	Egelhoff v. Egelhoff, 532 U. S. 141, 147 (2001)	Act 900 requires PBMs to reimburse pharmacies at a price equal to or higher than that which the pharmacy paid to buy the drug from a wholesaler	Ark. Code Ann. 17-92- 507(c)(2), (c)(4)(A)(i) (b), (c)(4) (C)(i)(b)	No	Act 900 merely a form of cost regulation, and Act 900 will not dictate plan choices. Further, "cost uniformity was almost certainly not an objecting of pre-emption."	
Rutledge	ERISA	"Refer to" Application	Gobeille v. Liberty Mutual Ins., 577 U.S. 312 (2016)	"Act 900 defines a PBM as any ""entity that administers or manages a pharmacy benefits plan or program," and it defines a "pharmacy benefits plan or program," as any "plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services to individuals who reside in or are employed in [Arkansas].""	Ark. Code Ann. 17-92- 507(a)(7), (9)	No	Act 900 regulates PBMs whether or not the plans they service fall within ERISA's coverage.	
Rutledge	ERISA	"Impermissible connection" with ERISA due to enforcement mechanisms that directly affect central matters of plan administration and interfere with nationally uniform plan administration	Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020)	Act 900 requires PBMs to reimburse pharmacies based on acquisition costs.	Ark. Code Ann. 17-92- 507(c)(2), (c)(4)(A)(i) (b), (c)(4) (C)(i)(b)	No	Requiring PBMs to reimburse pharmacies at or above their acquisition cost does not require plans to provide any particular benefit to any particular beneficiary in any particular way	
Rutledge	ERISA	"Impermissible connection" with ERISA due to enforcement mechanisms that directly affect central matters of plan administration and interfere with nationally uniform plan administration	Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020)	Act 900 requires plan administrators to comply with a particular process, subject to deadlines, for appeals, and dictates the standard governing the resolution of an appeal. If the pharmacy is successful in its appeal, the plan may need to recalculate and reprocess how much it owes.		No	ERISA does not pre-empt "state-law mechanisms of executing judgments against ERISA welfare benefit plans, even when those mechanisms prevent plan participants from receiving their benefits."	
Rutledge	ERISA	"Impermissible connection" with ERISA due to enforcement mechanisms that directly affect central matters of plan administration and interfere with nationally uniform plan administration	Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020)	Act 900 permits pharmacies to decline to dispense a prescription if the PBM's reimbursement will be less than the pharmacy's cost of acquisition		No	This provision does not deny plan beneficiaries their benefits, it just requires PBMs to compensate pharmacies at or above their acquisition costs. When a pharmacy declines to dispense a prescription, the responsibility lies first with the PBM for offering the pharmacy a below-acquisition reimbursement.	
Rutledge	ERISA	"Impermissible connection" with ERISA due to enforcement mechanisms that directly affect central matters of plan administration and interfere with nationally uniform plan administration	Rutledge v. Pharm. Care Mgmt. Ass'n, 141 S. Ct. 474 (2020)	Act 900 has a variety of enforcement mechanisms to ensure compliance with the Act		No	Enforcement mechanisms may result in "inefficiencies," but "creating inefficiencies alone is not enough to trigger ERISA pre-emption."	

CASE	PART D	RELATED FEDERAL STANDARD	CITATION	OK PATIENT RIGHT TO PHARMACY LAW ACT PROVISION OR N.D.	CITATION	REEMPTED?	COURT'S REASONING	STATE CONCEDED PREEMPTION
Mulready	Part D	Geographic restrictions for pharmacy networks	42 C.F.R. 423.120	Retail-Only Pharmacy Access Standards	Okla. Stat. 36, 6961(A), (B)	Yes	The OK Law would govern Part D standards for negotiated prices and negotiations with pharmacies, so the OK Law is preempted	
Mulready	Part D	Any willing provider terms	42 U.S.C. 1395w-104(b)(1) (A); 42 C.F.R. 423.505(b) (18) (terms and conditions must be reasonable and relevant)	Any Willing Provider provision	Okla. Stat. 36, 6962(B) (4)	No	The OK Law governs the preferred network, not the standard network, so no preemption	
Mulready	Part D	Preferred Pharmacy Network Standard	42 C.F.R. 423.120(a)(9)	Affiliated Pharmacy Prohibition and Network Provider Restriction	Okla. Stat. 36, 6961(C)	No	Part D's Standard states that a Part D plan may include a preferred pharmacy network, but does not regulate or provide any standards as to how the networks are managed or structured	
Mulready	Part D	Non-interference between Part D sponsors and pharmacies, prohibitions on price structure or formulary requirements for Part D drugs	42 U.S.C. 1395w111(i) (Non- interference provisions); 42 C.F.R. 423.100 (negotiated prices definition); 42 C.F.R. 423.464(a) (plans obligated to comply with CMS administrative processes)	Service Fee Prohibition, Affiliated Pharmacy Price Match, Post-Sale Price Reduction Prohibition	Okla. Stat. 36, 6962(B) (2)	Yes	The OK Law would govern Part D standards for negotiated prices and negotiations with pharmacies, so the OK Law is preempted	
Mulready	Part D	Quality assurance standards	42 C.F.R. 423.153(c) (Quality Assurance Standards)	Probation-Based Pharmacy Limitation Prohibition and Termination Payment Requirement	Okla. Stat. 36, 6962(B) (5), (7)	No	The OK Law does not act with respect to the quality assurance standards	
Mulready	Part D	Monitoring requirements for Part D sponsors	N/A	Contract Approval Rule	Okla. Admin. Code 365:25-29- 9(c) (1)	No	The OK Law requires insurers that use a PBM approve contracts used by the PBMs with retail pharmacies, and Part D acts on contracts between plan sponsors and PBM	
Mulready	Part D	N/A	N/A	Health Insurer Monitoring Requirement	Okla. Admin. Code 365:25-29- 9(c) (1)	PCMA failed to make a showing of injury, so no standing to challenge this provision		
Mulready	Part D			Promotional Materials Provision		Yes		Yes
Mulready	Part D			Cost Sharing Discount		Yes		Yes

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Tufte (district court opinion prior to Wehbi)	Part D	Disclosure obligations	42 C.F.R. 423.514(d); 42 U.S.C. 1320b-23	Requires certain PBMs to report to plan sponsors any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor	N.D. 16.2(2)	Yes	The disclosure obligations overlap (federal law requires disclosure to plan sponsors including information to plan sponsors, including the number of prescriptions dispensed, the amount of rebates, discounts, or price concessions the PBM negotiates and passes through to the plan sponsor, and the difference between the amount the PBM pays the pharmacy and the plan sponsor)	Yes - District Court held this standard pre-empted, and N.D. did not challenge on appeal
Wehbi	Part D	Part D plans shall permit any pharmacy to participate in a network if it meets the terms and conditions of the plan	42 U.S.C. 1395w-104(b)(1) (A); 42 C.F.R. 423.505(b) (18) (terms and conditions must be reasonable and relevant)	N.D. laws regulating PBMs, generally	N.D. 19-02.1- 16.1, 16.2	No	The federal standards do not require total federal control; in fact, there is intent for states to govern what plans and PBMs demand of pharmacies	
Wehbi	Part D	Non-interference between Part D sponsors and pharmacies, prohibitions on price structure or formulary requirements for Part D drugs	42 U.S.C. 1395w-111(i)	PBMs are prevented from prohibiting a pharmacy from dispensing drugs, and PBMs are prohibited from charging certain fees	N.D. 16.2(5); N.D. 16.1(3)	No	The Part D standards preempts laws that regulated negotiations between which drugs the pharmacy must carry and what prices the pharmacy may charge for the drugs	
Wehbi	Part D	Standards regulating formularies	42. C.F.R. 423.120(b)	Prohibition on PBMs from dispensing any/all drugs allowed under its license	N.D. 16.2(5)	No	Authorizing pharmacies to dispense all drugs allowed under their license does not regulate which drugs a Plan must cover	
Wehbi	Part D	Notice/comment exchange with CMS wherein CMS expressed concern about contracting terms that prohibit pharmacies from mailing prescriptions	83 Fed. Reg. 1695	Prohibition on PBMs prohibiting pharmacies from mailing drugs and charging S&H fees	N.D. 16.1(8)- (9)	No	It was unclear that the notice/comment constitute federal standards, or that they conflict with the ND law in any way	
Wehbi	Part D	Requirement to disclose certain information to patients; prohibition from prohibition on disclosing information to patients	42 U.S.C. 1395w-104(a) (1); (m)	PBMs cannot prohibit pharmacies from disclosing information to patients	N.D. 16.1(7); (5)	Yes	The state conceded that the N.D. law regulates the same subject matter	Yes
Wehbi	Part D	Requirement to disclose information to federal agencies	42 C.F.R. 423.514(d)	PBMs are required to disclose information to pharmacies upon request	N.D. 16.1(10)	No	Disclosures to federal agencies are different than disclosures to pharmacies	
Wehbi	Part D	Requirement that plan sponsors have a drug utilization management program and quality assurance measures	42 U.S.C. 1395w-104(c)(1) (A)-(B)	PBMs must utlize an improvement platform to aid in pharmacy performance measures	N.D. 16.1(3)	Yes	The N.D. law regulates quality assurance measures and performance incentives, which is the same subject matter as the federal law	
Wehbi	Part D	Standards governing the collection of retroactive pharmacy fees	42 C.F.R. 423.464(f)(6)	PBMs cannot directly or indirectly charge a pharmacy any fees that are not apparent at the point of sale	N.D. 16.1(2)	Yes	The N.D. law regulates the same subject matter	
Wehbi	Part D	Standards regulating copayments	42 C.F.R. 423.104(d)(2)(i)-(iii)	PBMs are prevented from clawing back copayments from pharmacies	N.D. 16.1(4)	No	There is no federal standard that governs who gets to keep a copayment	

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Wehbi	Part D	Regulations governing conflicts of interest	42 C.F.R. 423.504(b)(4) (vi)(G)	PBMs cannot have an ownership interests in a patient assistance program or a mail order pharmacy (unless they recuse themselves from any benefit from transactions between the entities)	N.D. 16.2(3)	No	The regulations refer to different kinds of conflict of interest	
Rutledge (8th Cir.)	Part D	The Negotiated Price Standard defines "negotiated prices" for Part D drugs as the price: "the part D sponsor (or other intermediary contracting organization) [such as a PBM] and the network dispensing pharmacy have negotiated as the amount such network entity will receive, in total, for a particular drug." Negotiated prices are "inclusive of all price concessions from network pharmacies" but "exclude[] contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale."	42 U.S.C. § 1395w-102; 42 C.F.R. § 423.100	Act 900 requires PBMs to reimburse pharmacies based on acquisition costs, and requires that the price paid by pharmacy customers be no less than the price negotiated by the pharmacy with its wholesaler.	Ark. Code Ann. 17–92–507(b) (4)(A)(i)(b); (C)(iii)	Yes	Act 900 acts "with respect to" the Negotiated Price Standard by regulating the price of retail drugs.	
Rutledge (8th Cir.)	Part D	Pharmacy Access Standard, which provides that a prescription drug plan "shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary)."	42 U.S.C. § 1395w–104(b)(1) (C); 42 C.F.R. § 423.120(a)	Act 900 has a "decline to dispense" clause that permits pharmacies to decline to dispense drugs if they will not be reimbursed above cost	Ark. Code Ann. 17–92– 507(e)	Yes	Act 900 acts "with respect to" the Pharmacy Access Standard, because a pharmacy that refuses to dispense drugs becomes, in effect, an out-of- network pharmacy.	