IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF ARKANSAS

CENTRAL DIVISION

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA — PLAINTIFF

v. — No. 4:21-CV-864-LPR

ALAN MCCLAIN, in his official capacity as Commissioner of the Arkansas Insurance Department, and — DEFENDANT

Community Health Centers of Arkansas; and Piggott Community Hospital — INTERVENOR-DEFENDANTS

BRIEF IN SUPPORT OF DEFENDANT AID'S RESPONSE TO PLAINTIFF'S COMBINED REPLY

The Defendant, Alan McClain, in his official capacity as Commissioner of the Arkansas Insurance Department ("AID"), submits the following Response Brief to Plaintiff's Combined Reply.

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## INTRODUCTION

This Court's review of all of the parties' extensive briefs filed in this proceeding, at the very least, should reveal that there exists a legitimately, debatable issue of whether Act 1103 impliedly conflicts with the Federal 340B drug pricing legislation and violates the Federal Supremacy Clause. As such, given that there are genuine, good faith areas of debate, the Plaintiff is not entitled to and does not qualify for the drastic remedy of an Order for Summary Judgment under Rule 56, *as a matter of law*. (Emphasis Added) This Court should deny Plaintiff's Motion for Summary Judgment, because there exist genuine, legal issues on preemption, and allow the parties to next argue whether Act 1103 infringes upon the Federal "Commerce Clause."

Act 1103 is not a "pricing" statute. The 340B federal legislation in 42 U.S.C. 256b is however a "pricing" statute. While the parties were filing briefs on the issue of federal preemption, AID issued Rule 123 which makes it clear that Act 1103 is only policing the "delivery" and "acquisition" of 340B drugs pertaining to third party, pharmacy contracts with covered entities issued in this State. Rule 123 operates with the full effect and force of law. Neither Act 1103 or AID Rule 123 impact, conflict or interfere with the federally regulated scheme within the 340B program that relate to federally regulated 340B parameters of: (1) ceiling price calculations, (2) diversion limitations, (3) duplicative discount prohibitions, (3) civil and compensatory penalties, (4) arbitration provisions, (5) audits, or finally, (6) registration or licensing of participants in the 340B program. Act 1103 does not supplant or upend these federal parameters. Act 1103 is a state law which only governs or applies to third party, commercial contracts of Arkansas based pharmacies with covered entities, issued in this State. Third party pharmacies have no federal penalty or compensatory relief mechanisms to collide with, as none are offered. Nor is the State under Act 1103 engaged in making predeterminations in conflict with the 340B program or

regulating "overcharging" in its state role to regulate third party contract arrangements with covered entities participating in the 340B program.

Act 1103 and Rule 123 trade practice penalties do not collide with the 340B program administrative penalties. State law penalties under Act 1103 and Rule 123 only apply to pharmacy manufacturer cancellation of state-based commercial, private contracts of Arkansas pharmacies with Arkansas covered entities. Federal or HRSA penalties apply to all of the other activities under its federal purview. A state can regulate these third party contracts on the state level, and HRSA can regulate the 340B restrictions and penalties on its federal level, in harmony, without any collision or conflicts.

Act 1103 does not open the "barn door" to legalizing distribution of FDCA controlled drugs, or any other public health and safety restrictions. Act 1103 does not conflict with the FDCA's restriction to REMS drugs. Act 1103's application should be construed narrowly and not broadly, as Plaintiff maintains.

Lastly, the Plaintiff's cited cases are not on point, or "on all fours" with any issue raised specifically in this proceeding, as the issue of federal preemption of state laws applying to third party, pharmacy contracts is not before, and has not been before any Court. Even if the cases provide some circumstantial relevance to this proceeding, the federal schemes in such cases are not equivalent with the 340B scheme in this matter. The federal scheme in 340B is expressly silent as to the role states may play in policing or regulating the private market of third party issued, commercial contracts issued in that state pertaining to the 340B program.

## ARGUMENT

### I. Pricing Phraseology In Act 1103 Is Not Dispositive to Preemption

The Plaintiff argues that because the title and pertinent section(s) to Act 1103 contain phraseology explicitly referencing "pricing," it necessarily means that Act 1103 is a "pricing" statute and not a delivery or distribution statute. This is simply not the case for three separate reasons.

First, in its title and in various sections, although Act 1103 does reference "pricing," the Arkansas General Assembly is simply trying to caption and accurately identify the federal program at issue in a brief phrase throughout the Act, and not declare in the modifier, "pricing," that it was engaged in imposing price controls over 340B drugs. The Federal legislation establishing the 340B-drug pricing program, after all, is entitled, "Limitation on Drug *Pricing* By Covered Entities," and the word, "*pricing*," in the phrase, 340B *drug pricing* is referenced in the Federal program legislation, and in various HRSA publications, as *the 340B drug pricing program*. (Emphasis Added). The Arkansas Legislature is captioning this phrase to quickly label the Federal program at issue throughout the Act. The Plaintiff is therefore grossly exaggerating the effect of this captioning or phraseology in its Reply that the Arkansas Legislature intends to engage in price controls. This Defendant in fact invites this Court to compare the entire Federal legislation establishing this program with that of Act 1103, and it is abundantly obvious that it is the Federal legislation and not Act 1103 which establishes a pricing scheme for the 340B drugs with covered entities. Only one, single subsection in Act 1103, now codified in Ark. Code Ann. § 23-92-604(c), addresses the contracts of pharmaceutical manufacturers with covered entities, and the remaining parts of the legislation pertain to the activities of pharmacy benefit managers. This single subsection does nothing more than forbid or prohibit pharmaceutical manufacturers from cancelling contracts between covered entity hospitals and their contracted pharmacies. It is entirely silent on the "pricing" calculations or methodologies required, and woefully anemic in its structure to consider it to be a "pricing" statute.

Secondly, the Plaintiff blatantly ignores a cardinal rule of statutory construction, by interpreting Arkansas legislation titles and section titles as a guide to the meaning of the statutory language at issue. In terms of the Arkansas Insurance Code, where this legislation is actually placed in the Arkansas Code, Ark. Code Ann. § 23-60-107, provides a warning, for its provisions, that its titles and captions including

section headings are not to be used for interpreting the meaning of the provisions underneath such headings. This section states: "the scope and meaning of any provision shall not be limited or otherwise affected by the caption or heading of any chapter, section or provision."

Thirdly, and most importantly, no truer indication of the Arkansas General Assembly's intent that Act 1103 is a distribution and delivery statute, and not a pricing control, is better demonstrated than in the recent AID Rule implementing Act 1103.

AID recently finalized and promulgated Rule 123, "340B Drug Program Nondiscrimination Requirements," effective September 30, 2022, while the parties in this litigation were filing briefs. This Rule, which implements the statute itself, is clear in Section 2(7) that Act 1103 pertains to "the *acquisition and delivery* of 340B-priced drugs as established under Section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585." (Emphasis Added) (See Exhibit "A", to this Reply). The Arkansas Legislative Council, and Subcommittee on Rules and Regulations, reviewed and approved this exact language in its approval of the Rule on September 16th, 2022. The Act is an **acquisition and delivery** statute and not a system of pricing controls. (See Exhibit "B") (Emphasis Added). The Plaintiff does not challenge the validity of the Rule; however, in a mere footnote in its Reply to the rulemaking language, instead of disputing the clear intent of the State Legislature in its review and approval of the rule, and this exact language, simply bemoans this development, and dismisses it off hand as a "linguistic sleight of hand." (Plaintiff's Brief, P. 16)

This Defendant agrees the proposed Rule added "linguistics" to the enforcement of the Act. But there is no "sleight of hand," subterfuge or trickery. The Plaintiff itself participated in the recent, proposed rule-making of Rule 123. The Plaintiff submitted its original Motion and Brief for Summary Judgment into the administrative record for the proposed Rule and never raised an objection in its submissions, to the particular, or exact AID proposed language narrowing the scope of Act 1103 to the "acquisition and delivery" of 340B-priced drugs; nor did the Plaintiff testify specifically in opposition to Section 2(7) of this particular language at the Legislature when it was undergoing review and approval at

that stage on September 17, 2022 at the Arkansas Legislative Council. The Plaintiff cites admissions by AID in its footnotes that its language decisions in the Rule are in response to federal pre-emption claims; but, as explained in the previous reply, AID is a public regulator responsive to all publicly raised concerns including those raised by this Plaintiff, but, at the end of the day, the Plaintiff demanded no compromise language solution(s) and wants to be 100% free of state regulation.

Today, the Plaintiff complains about the "linguistics" in AID Rule 123, Section 2(7); however, the fact is, validly promulgated agency rules have the full force and effect of law. Rules issued through the notice-and-comment process are often referred to as "legislative rules," because they have the force and effect of law. Chrysler Corp. v. Brown, 441 U.S 281, 302-303, 99 S.Ct. 1705, 60 L.Ed.2d 208 (1979); Perez v. Mortgage Bankers Ass'n., 572 U.S. 92, at 96, 135 S.Ct. 1199, 191 L.Ed.2d 186 (2015); Clonlara, Inc., v. State Bd. of Educ., 442 Mich. 230, at 240 (1993); Azar v. Allina Health Services, 139 S.Ct. 1804 at 1806, 204 L.Ed.2d 139 (2019). Additionally, under state law, state agency rules are entitled to deference by the Courts. Nucor Steel-Arkansas v. Arkansas Pollution and Ecology Commission. 2015 Ark. App. 703, 478 S.W.3d 232, at 240 (Ark.App. 2015). Administrative appeals give great deference to the agency's expertise, based on the recognition that such agencies are better equipped by specialization, insight through experience, and more flexible procedures to determine and analyze legal issues affecting them. See Pine Bluff for Safe Disposal v. Ark. Pollution Control & Ecology Comm'n, 354 Ark. 563, 127 S.W.3d 509 (2003). Agency decisions will be upheld if they are supported by substantial evidence and are not arbitrary, capricious, or characterized by an abuse of discretion. *Id.* On appeal, Courts give the evidence its strongest probative force in favor of the agency's findings. *Id.* Even where issues of law are concerned, Courts often accord deference to the agency's ruling, particularly when reviewing the agency's interpretation of statutes or its own rules and regulations. See Lamar Outdoor Advert. v. Ark. Hwy. & Transp. Dep't, 86 Ark. App. 279, 184 S.W.3d 461 (2004).

Lastly, the Plaintiff argues that a statute which limits or controls delivery or acquisition of the 340B drugs necessarily establishes or guarantees with it the pricing of the drugs delivered. The Plaintiff

provides the example of a delivery of an automobile and says, "I may not be able to force you to sell me a car for $1.00 but I can force you to deliver to me a car priced at $1.00," this is, in Plaintiff's words, "a distinction without a difference." Actually, there is a glaring difference between the pricing and sale permitted and the delivery or shipment of the item. Forget for a minute that the Plaintiff's analogy does not involve third party vendors, as the 340B program has with contract pharmacies, but taking the Plaintiff's own ridiculous, irrelevant example, the price of the car, the amount of the trade-in, the credit and lending disclosures, the discounts provided, the rebates, the sales tax, the consumer required disclosures, all of which go into the process in the sale of a car are initially and separately negotiated, or even regulated by various federal or state agencies or laws. The act of delivery or shipment of the car itself is an entirely separate component or step of that transaction. There is a delivery of the automobile to the consumer, and it may very well carry with it, a delivery embedded at a "contracted price" the parties earlier arrived at, but the pricing and sale requirements are initially and separately established between the parties, independent of delivery. Hence, for a 340B drug, the "ceiling price" requirements, and any other Federal 340B pricing methodologies (rebate amounts or average wholesale pricing scales) employed in the calculation of the pricing, are initially regulated and set by federal law; however, the actual delivery or distribution or shipment of the drugs themselves can easily be governed separately by state law without conflicts. Federal law still governs the pricing of the 340B drugs, the qualifications or limitations as to participation in the 340B program for that pricing, the overcharging, diversions and duplicative discounting, but state law operates on the shipment and delivery of the drugs to third party outside pharmacies in contract with covered entities. The Plaintiff's analogy to car sales is not only irrelevant but also contradicts its own conflicts analysis.

## II. Act 1103 Is A Delivery Statute That Is Still Not Preempted

For good reason, in light of the recently finalized Rule 123 by AID, the Plaintiff admits in its brief, even if Act 1103 is a delivery or acquisition statute, it still conflicts with the Federal 340B program. Its argument is essentially that a state delivery requirement collides with the federal program by forcing

the sale, re-sale or transfer of the 340B discounts to third parties ("contract pharmacies") which are not covered entities or patients of covered entities in violation of the Federal Act. In Plaintiff's view, therefore, any transfers of 340B discounted drugs to covered entity contract pharmacies are themselves prohibited, illegal "diversions." The Plaintiff's argument however conflicts with enforcement letters of HHS and HRSA, a 2020 Advisory Opinion by HHS, earlier "Guidances" issued by HHS, and ultimately trips into current, pending litigation about the legalities of such pronouncements by HHS brought by various Plaintiff members against HHS. See Eli Lilly Company, et al. v. United States Department of Health and Human Services, No. 1:21-cv-00081-SEB-MJD (S.D. Indiana 2021); Novartis Pharmaceuticals Corporation v. Espinoza, No. 21-cv-1479 (D.C. Cir, 2021); and Sanofi-Aventis U.S., LLC v. U.S. Department of Health and Human Services, 570 F.Supp3d 129 (New Jersey D.C. Cir, 2021). Many of these cases and others are currently pending on appeals and involve various Courts reviewing the validity of the HHS interpretations under the Federal Administrative Procedures Act or "APA." Although the cases do not pertain to a review of the exact issue in this case related to federal preemption of a state law requiring recognition of a covered entities third party contracts with pharmacies, it is undisputedly clear that the federal arbiters in this matter have already weighed in on this matter and concluded that contract pharmacies are lawful or legal delivery agents for covered entities in the 340B program, and that pharmaceutical manufacturers must honor covered entity contracts with outside contract pharmacies.

When confronted with the Defendants' salient points that Congress was actually silent as to the use of delivery agents in the 340B program by covered entities, and that HHS and HRSA have themselves stated in enforcement letters that contract pharmacy contracts are to be honored by pharmaceutical manufacturers in the 340B program, the Plaintiff dismisses the congressional silence in its brief, as a mindless "paralysis" by Congress, explaining that "congressional silence frequently betokens unawareness, preoccupation, or paralysis." (See Plaintiff's Br. P. 20) However, a more simple, common sense view of the "silence," is simply that Congress betokens or affirmatively permitted such arrangements, or acquiesced, as it has for many years since the inception of the 340B program. The

Plaintiff wants to have its cake and to eat it, too. On the one hand, the Plaintiff champions HRSA and HHS as "exclusive arbiters" of a comprehensive, preemptive federal scheme throughout its briefs in this litigation, but on this issue of the pharmacies being valid delivery agents of the covered entities, the Plaintiff maintains that the "exclusive arbiters" are wrong! As stated previously in its Reply, the Plaintiff and its members simply do not want to be regulated in the contracting space concerning contract pharmacies, on all fronts, whether it be by state authorities or federal.

III. The Presumption Against Federal Preemption Is Alive and Well

The Plaintiff next dismisses a long line of court precedent establishing a presumption against federal preemption against state laws in areas where states have traditionally regulated. Farina v. Nokia, 625 F.3d 97 115, at 116 (3d Cir. 2010). In fact, the presence of federal regulations, however longstanding, does not by itself defeat the application of the presumption. Rather, its application accounts for the historic presence of state law, but does not rely on the absence of federal regulation. *Id.* at 116. In other words, the presumption against preemption will not be vitiated by a history of federal regulation, alone, but rather, by the absence of a history of state regulation. In all pre-emption cases, and particularly those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest. Wyeth v. Levine, 555 U.S. 555, at 565 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

This is particularly the case where there is no expressed preemption language as is absent with the 340B program. As Justice O'Connor explained in her opinion for a unanimous Court: "the case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there is between them." Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 166–167, 109 S.Ct. 971, 103 L.Ed.2d 118 (1989); Wyeth v. Levine, 555 U.S. 555, at 574 129 S.Ct. 1187,

173 L.Ed.2d 51 (2009). Indeed, in as much as Plaintiff spends pages and pages of its Briefs detailing the federal exclusivity, history, comprehensive federal nature of the 340B program, and the impending doom to the program, from exaggerated conflicts if there were state regulation of aspects of the 340B contracts, we have to ask, if that really is the case, why is there then no expressed preemption against state action in the 340B Program, or even partial expressed federal preemption? The answer is that Congress wants to permit it.

Act 1103 seeks to prohibit or limit pharmaceutical manufacturer exclusions for covered entity hospitals with outside pharmacies in this State; as such, the Act is clearly regulating the space of state-based commercial contracts or arrangements traditionally left to state regulation or police powers. These commercial contracts actually do impact the practices of pharmacies, as they interfere with their administrative relationships with hospitals in this State. Although the Plaintiff dismisses language in Wehbi, as a mere one line comment by the 8th Circuit, the Court, in reviewing Medicare and ERISA preemption claims by pharmacy benefit managers, clearly holds that the practice of pharmacy "is an area traditionally left to state regulation." Pharmaceutical Care Management Association v. Wehbi, 18 F.4th 956, at 972 (2021). The "practice" of pharmacy must include and should include how pharmacies actually "practice" in their professions in business contracts or relationships with medical providers.

## IV. Act 1103 Does Not Conflict With The FDCA

The Plaintiff continues to dramatically worry that Act 1103 compels or forces pharmaceutical manufacturers to deliver FDCA restricted drugs to covered entities, subject to REMS provisions. The Plaintiff now goes so far as to scare all of us and suggests that, given the absence of an expressed legislative exclusion for REMS subject drugs in Act 1103, the Arkansas Supreme Court would be automatically compelled to interpret Act 1103 so broadly that the Court would have no choice but to actually compel manufacturers, healthcare providers and pharmacies to outrightly violate or defy federal law by mandating the delivery of drugs subject to REMS. To help support this bizarre proposition, the

Plaintiff has grabbed a few sentences from the Arkansas Supreme Court on statutory construction in Myers v. Yamato Kogyo Company, Ltd., 597 S.W3d 613 (Ark. 2020). In Myers, the Arkansas Supreme Court is actually construing a workers compensation law to determine if immunity applied to parent owners of companies under the state workers compensation system. The case, first of all, has absolutely nothing to do with federal preemption issues; but the Plaintiff presses on and quotes the Court in that case, that "in considering the meaning and effect of a statute, we [the Court] construe it just as it reads, giving the words their ordinary and usually accepted meaning in common language." Myers, at 617. What the Plaintiff however fails to quote in this very, exact, same case are the next statements by the Court that it applies "strict construction," and "strict construction is narrow construction and requires that nothing be taken as intended that is not clearly expressed." *Id.*, at 167. See also Lawhon Farm Servs. v. Brown, 335 Ark. 272, 279, 984 S.W.2d 1, 4 (1998). Putting both statements together, the Court is to construe a statute according to its actual language, but to do so narrowly and not infer intent unless it is clearly expressed. In this vein, absolutely nothing in Act 1103 expressly refers to the Act mandating or intending to mandate the delivery of federally prohibited drugs. The Plaintiff wants to "infer" this requirement in the absence of clearly expressed language. Act 1103 is not intending to nullify or supplant FDCA controls.

The Plaintiff's same misplaced anxieties could in fact be had for conflicts arising with any other licensing or public health and safety laws, and not just the FDCA. Act 1103, after all, does not also either provide an exclusion for delivery of the 340B drugs to unlicensed or unregistered hospitals or unlicensed pharmacies. Are we thereby also inferring that Act 1103 requires or allows for unlicensed entities to engage in 340B drug deliveries? No, of course not. The Defendants address this issue in their replies, the FDCA and other public health and safety laws or measures continue to apply to the drugs, and there is simply no conflict with the FDCA or any other public health and safety law.

## V. Federal and State Penalties Do Not Conflict

The Plaintiff next argues that AID's trade practice penalties for violations of Act 1103 (imposed via Rule 123) directly conflict with the civil penalty provision(s) empowered to HRSA which permit HRSA to seek monetary, administrative sanctions on manufacturers or covered entities in the administration of the 340B Program. Not surprisingly, the Plaintiff appears to concede, as it has to actually concede, that the separate HRSA remedial or compensatory remedies, including equitable ones, are indeed available to covered entities and manufacturers through the HRSA Rule-based arbitration process, but not for contract pharmacies in this scheme. We must therefore ask, if no remedial, compensatory, or punitive penalty relief is provided for third party pharmacies at the federal level, what are the state-based penalties conflicting with at the federal level for contract pharmacies?

The Plaintiff nonetheless still complains that a state-based punitive, penalty provision conflicts with similar HRSA punitive penalties, even with third party contracting pharmacies, and this complicates or frustrates federal objectives and administration. The Plaintiff warns all of us of a dire "collision course" looming on the horizon if we permit the state penalties imposed under Act 1103 or Rule 123. As is its briefing habit, the Plaintiff once again exaggerates conflicts. There is no collision or conflict at all. Act 1103 only restricts exclusions by manufacturers as to third party contracts of 340B hospitals with outside, Arkansas-based community pharmacies. Any penalties AID or Arkansas state law would impose would relate to a manufacturer's cancellation of a covered entity contract with an outside pharmacy which would violate State law. Neither AID nor the State of Arkansas would have any larger role or even legal authority to impose penalties on manufacturers for "overcharging" or impose penalties on covered entities or manufacturers for improper diversions or duplicative discounts, activities all of which are subject to penalties or fines under the purview of HRSA. The penalties do not conflict because the underlying conduct, prompting the penalties, does not match.

The Plaintiff raises two additional points about its perceived "collision course" between state and federal enforcement, both of which are in the same vein of exaggerated conclusions we saw from its earlier claims about the FDCA preempting Act 1103.

First, citing no HRSA or HHS enforcement provision or policy whatsoever, or any federal provision in the 340B legislation, the Plaintiff maintains that a manufacturer's own failure to honor or comply with outside pharmacy contracts with covered entities on 340B drugs, which would violate Act 1103, would *itself* result in an "overcharging" violation by the manufacturer under federal law. (Emphasis Added) The Plaintiff states in its introduction, "in reality, Act 1103 attempts to penalize manufacturers for (in the State's eyes) overcharging for 340B drugs." (Plaintiff's Brief, P.10). The Plaintiff later in its Brief attempts to explain this better for us in in this supposition: "if contract pharmacy purchases are actually covered entity purchases, as AID and Intervenors contend, then it would *seem to follow* that a manufacturer *overcharges* a covered entity by denying 340B drug pricing for contract pharmacy purchases and instead selling the drugs at a normal commercial rates." (Emphasis Added) (Plaintiff's Brief P. 30) Therefore, the Plaintiff concludes that Act 1103, *it seems*, is in reality intervening in the enforcement of "overcharging," under the purview on the other hand of HRSA, and prohibited under federal law. (Emphasis Added) Of course, a more apt, day-to-day, realistic example of "overcharging" in the 340B system is when all of third party contracts are actually in effect and in-place, but a manufacturer has neglected to provide the 340B drug at or below the "ceiling price" to the covered entity. Naturally, the Plaintiff does not want to use a more normal example of "overcharging." But, accepting the Plaintiff's own "supposition" here, HRSA and the State simply regulate or exist in their own spheres. In this scenario, the covered entity or third party outside pharmacy simply files a complaint at AID against the manufacture on the cancellation of the third party contract for violation of Act 1103, and the covered entity files a complaint or a request for arbitration with HRSA under the 340B system for "overcharging."

The Plaintiff's second point about this perceived collision between state and federal enforcement is that because AID has to make a "pre-determination" in its enforcement of Act 1103 that an "entity [is] authorized to participate in 340B drug pricing," there is an irreconcilable conflict. The Plaintiff explains that for AID to find a violation of Act 1103, AID must first determine that the manufacturer in question had an obligation under the federal statute to provide 340B discount drugs to the covered entity who has a

contract with a pharmacy, *that a covered entity was authorized to participate in the program*. (Emphasis Added) (Plaintiff's Brief, Pages 32-33). The Plaintiff again is making a mountain out of a proverbial molehill. The Arkansas General Assembly, at least on this particular clause, is simply ensuring that covered entities with contracts with outside pharmacies be authorized, licensed or registered in the federal program system. Covered entities, after all, do have to be registered or licensed with HRSA or HHS to participate in this program. This is simply a precautionary measure. The State simply does not want to confer the state benefit of enforcement rights to third party pharmacies with covered entity hospitals which are not registered in the 340B federal system. In its enforcement, AID can simply require the covered entity hospital to show proof of its registration in this matter.

It is fortunately not true in all cases that both state and federal authorities cannot mutually regulate or coordinate their own respective, separate spheres of obligations under federal and state laws. AID does this same balancing act everyday with Medicare Advantage Companies ("MAPs") under the Federal Medicare & Modernization Act, in which there is expressed preemption. AID or the State regulates the financial solvency and producer licensing of the activities of the MAPs under state law, and CMS regulates the network operations and benefits required to be provided by the MAPs under federal law. The same example applies to ACA or Affordable Care Act federal mandates. CMS establishes the federal mandates, and the states review and approve that such mandates are providing covered benefits in state-regulated insurance contracts at the state level, under rates established by the states.

In conclusion at least as to this section of the argument, the penalties and enforcement do not conflict, and the penalty relief in the federal scheme certainly does not for outside, third party pharmacies who are left entirely out of the loop in this system. This Defendant already previously copied and pasted the HRSA ADR Rule in its last Reply in significant parts. As previously stated, at least related to the ADR process and companies allowed to participate in this federal process, the scheme is virtually entirely compensatory or remedial in nature, related to "overcharging" claims or duplicative discounting claims and grievances made between *pharmaceutical manufacturers or covered entities only*. (Emphasis Added)

Third party contract pharmacies, or outside pharmacies with contracts with covered entity hospitals are, on the other hand, simply not provided any direct standing, pathway or federal avenue whatsoever to either file complaints with HRSA under either the HRSA civil penalty process or ADR program. They are knocked out of the "loop," scheme or process. Act 1103 alternatively provides a state-based pathway for third party pharmacies to file complaints when pharmaceutical manufacturers terminate such third party contract relationships with covered entities. Secondly, Act 1103 does not necessarily require the State to make conflicting or dual, pre-determinations of 340B federal requirements, in assessing the federally required pricing, or ceiling prices, in its review and enforcement of such complaints, related to the calculations of the pricing of the 340B drugs to be delivered or acquired by contract pharmacies.

## VI. Plaintiff's Reliance on Buckman or Astra as Controlling Is Misplaced

The Plaintiff continues to rely on Astra USA, Inc. v. Santa Clara Cty., Cal., 563 U.S. 110 (2011) and now, more recently with Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001). Both cases are applauded, or self-described by the Plaintiff in various spots of its Reply Brief, to be "on-point" or "on all fours," or favorably cast as, "not easily dismissed," with the current pending litigation in front of this Court. However, this is woefully not the case, as none of these cases are on "all fours" with the exact preemption issued raised in this proceeding which involves a court review of separate, state statutory law allegedly conflicting with the 340B federal legislation.

Arkansas is fortunately or unfortunately the first pioneer in line on this preemption issue with Act 1103.

Surprisingly, the Plaintiff actually admits that Astra is not a preemption case even though the Plaintiff states, "it involved a very similar question." Actually, we partially agree, Astra is not a preemption case, but we disagree it involved a "very similar question." It does not involve a "very similar question." The case analyzes an entirely different question. Astra is not reviewing state police power penalties imposed in the State of California by a California state statute prohibiting exclusions with third

party pharmacy contracts. Astra is addressing suits for private causes of action by 340B entities related to "overcharging," by third party beneficiaries, for which there already is a federal compensatory administrative remedy under federal law. Here, as stated previously, the state law restriction at issue in Arkansas does not seek to impose compensatory or monetary relief, but applies state punitive penalties over contract limitations or prohibitions of covered entity contracts with third party outside pharmacies, separately and unconnected with any available or entitled 340B Federal remedies or claims.

In Buckman, the Supreme Court impliedly preempted state tort fraud claims under the Food and Drug and Cosmetic Act (FDCA) brought against a manufacturer of bone screw devices for "fraud-on-the FDA ("Food and Drug Administration) claims." The Supreme Court held that State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. The Court explains:

"As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA."

Buckman, at 350-351.

The U.S Supreme Court goes on to further justify its implied preemption in Buckman by explaining the comprehensive role of the FDA in its broad jurisdiction to review public citizen reporting and complaints:

"The FDA is empowered to investigate suspected fraud, see 21 U.S.C. § 372; 21 CFR § 5.35 (2000), and citizens may report wrongdoing and petition the agency to take action, § 10.30. In addition to the general criminal proscription on making false statements to the Federal Government, 18 U.S.C. § 1001 (1994 ed., Supp. V),3 the FDA may respond to fraud by seeking injunctive relief, 21 U.S.C. § 332, and civil penalties, 21 U.S.C. § 333(f)(1)(A); seizing the device, § 334(a)(2)(D); and pursuing criminal prosecutions, § 333(a). The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration."

These same avenues, by the way, with the FDA are not available here for Arkansas based community pharmacies in their contracts with covered entities in the 340B Program. As this Defendant

has already pointed out, contract pharmacies, as third party contractors with covered entity hospitals, do not impose any "burdens" which dramatically increase the burdens on HHS or HRSA or the existing federal 340B system because they are simply not included in the federal scheme to "burden" anyone at the federal level, nor do they have any of these same corresponding federal pathways for relief, or remedies for relief under the HRSA rules or 340B program, as in Buckman, to report violations, to file claims or complaints for fraud, to pursue criminal prosecution, or injunctive relief. The Plaintiff's reliance on Buckman is therefore misplaced in this proceeding.

In conclusion, the arguments and cases raised or cited by the Plaintiff in its Reply to the Defendants' Combined Response(s) are not pertinent or relevant to support any Order for Summary Judgment for Plaintiff's preemption or Supremacy Clause claim(s).

WHEREFORE, Defendant prays that the Plaintiff's Motion For Summary Judgment be denied, and for all other just and proper relief to which Defendant may be entitled.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Booth Rand, do hereby certify that a copy of the foregoing has been mailed to the following person(s) on this 21 day of October, 2022:

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Booth Rand

# RULE 123

# 340B DRUG PROGRAM NONDISCRIMINATION REQUIREMENTS



## I. AUTHORITY

This rule is issued pursuant to Ark. Code Ann. § 23-92-606 which mandates that the Insurance Commissioner ("Commissioner") shall promulgate a rule to implement the subchapter pertaining to the 340B Drug Pricing Nondiscrimination Act.

## II. DEFINITIONS

As used in this Rule:

(1) "Arkansas-based community pharmacy" means a Pharmacy licensed and located in this State;

(2) "Covered entity" means an entity that meets the 340B Drug Pricing Program's eligibility requirements found at 42 U.S.C. § 256b(a)(4) and is enrolled in the 340B Drug Pricing Program;

(3) "Patient" means an individual who has an established relationship with a covered entity and is seeking medical diagnosis and treatment from the covered entity;

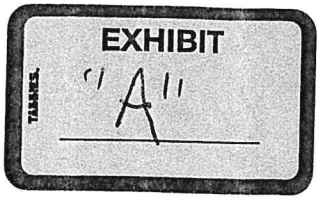
(4) "Pharmacy" means the same as defined in § 17-92-101;

(5) "Provider" means a licensed pharmacist as defined in § 17-92-101;

(6)(A) "Third party" means:

(i) A payor or the payor's intermediary;

or (ii) A pharmacy benefits manager.



(B) "Third party" does not include:

(i) The Arkansas Medicaid Program;

(ii) A risk-based provider organization as established under the Medicaid Provider-Led Organized Care Act, § 20-77-2701 et seq.; or

(iii) A self-insured governmental plan or a pharmacy benefits manager for a self-insured governmental plan; and

(7) "340B drug pricing" means the acquisition and delivery of 340B-priced drugs as established under section 602 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585.

## III. THIRD PARTY REQUIREMENTS

A third party shall:

(1) Inform a patient that the patient is not required to use a mail-order pharmacy;

(2) Obtain a signed waiver from a patient before allowing the use of a mail-order pharmacy;

(3) Make drug formulary and coverage decisions based on the third party's normal course of business;

(4) Allow a patient the freedom to use any pharmacy or any provider the patient chooses, whether or not the pharmacy participates in 340B drug pricing; and

(5) Eliminate discriminatory contracting as it relates to:

(A) Transferring the benefit of 340B drug-pricing savings from one (1) entity, including critical access hospitals, federally qualified health centers, other hospitals, or 340B drug-pricing participants and their underserved patients, to another entity, including without limitation pharmacy benefits managers, private insurers, and managed care organizations;

(B) Pricing that occurs when offering a lower reimbursement for a drug purchased under 340B drug pricing than for the same drug not purchased under 340B drug pricing;

(C) Refusal to cover drugs purchased under 340B drug pricing;

(D) Refusal to allow 340B drug-pricing pharmacies to participate in networks; and

(E) Charging more than fair market value or seeking profit sharing in exchange for services involving 340B drug pricing.

## IV. THIRD PARTY AND PHARMACEUTICAL MANUFACTURER-PROHIBITIONS

(a) A third party shall not:

(1) Coerce a patient into using a mail-order pharmacy;

(2) Require a patient to use a mail-order pharmacy;

(3) Discriminate, lower the reimbursement, or impose any separate terms upon a pharmacy in any other third party contract on the basis that a pharmacy participates in 340B drug pricing;

(4) Require a pharmacy to reverse, resubmit, or clarify a 340B drug-pricing claim after the initial adjudication unless these actions are in the normal course of pharmacy business and not related to 340B drug pricing;

(5) Require a billing modifier to indicate that the drug or claim is a 340B drug-pricing claim unless the drug or claim is being billed to the fee-for-service Arkansas Medicaid Program;

(6) Modify a patient's copayment on the basis of a pharmacy's participation in 340B drug pricing;

(7) Exclude a pharmacy from a network on the basis of the pharmacy's participation in 340B drug pricing;

(8) Establish or set network adequacy requirements based on 340B drug pricing participation by a provider or a pharmacy; or

(9) Prohibit an entity authorized to participate in 340B drug pricing or a pharmacy under contract with an entity authorized to participate in 340B drug pricing from participating in the third party's provider network on the basis of participation in 340B drug pricing.

(b) A third party that is a pharmacy benefits manager shall not base the drug formulary or drug coverage decisions upon the 340B drug-pricing status of a drug, including price or availability, or whether a dispensing pharmacy participates in 340B drug pricing.

(c) A pharmaceutical manufacturer shall not:

(1) Prohibit a pharmacy from contracting or participating with an entity authorized to participate in 340B drug pricing by denying access to drugs that are manufactured by the pharmaceutical manufacturer; or

(2) Deny or prohibit 340B drug pricing for an Arkansas-based community pharmacy that receives drugs purchased under a 340B drug pricing contract pharmacy arrangement with an entity authorized to participate in 340B drug pricing.

## V. PHARMACY CLAIMS

All pharmacy claims processed by a pharmacy that participates in 340B drug pricing are final at the point of adjudication.

## VI. PENALTIES

The penalties, actions or orders, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

## VII. EFFECTIVE DATE

This Rule is effective after review and approval by the Arkansas Legislative Council, ten (10) days after filing of the approved Rule with the Arkansas Secretary of State.

**ALAN MCCLAIN**
**INSURANCE COMMISSIONER**

9/19/2022
**DATE**

REPORT OF THE
ADMINISTRATIVE RULES SUBCOMMITTEE
OF THE
ARKANSAS LEGISLATIVE COUNCIL

September 16, 2022

Co-Chairs:

The Administrative Rules Subcommittee met on Thursday, September 15, 2022, at 9:00 a.m., in Room A, MAC.

1. The Subcommittee filed the attached reports from ALC Subcommittees concerning the review of rules.

2. The Subcommittee reviewed and approved the following rules filed pursuant to Ark. Code Ann. § 10-3-309:

   DEPARTMENT OF AGRICULTURE, COMMISSION ON WATER WELL CONSTRUCTION (Chris Colclasure; Wade Hodge; Blake Forrest)

   a. Supervision Rule

   DEPARTMENT OF COMMERCE, STATE INSURANCE DEPARTMENT (Booth Rand; Beth Barrington; Crystal Phelps)

   a. Rule 123: 340B Drug Program Nondiscrimination Requirements

   b. Rule 118: Pharmacy Benefit Managers Regulation

   DEPARTMENT OF EDUCATION, DIVISION OF HIGHER EDUCATION (Whitney James; Maria Markham)

   a. Rules Governing the Governor's Higher Education Transition Scholarship Program

   DEPARTMENT OF FINANCE AND ADMINISTRATION, REVENUE DIVISION (Paul Gehring; Joel DiPippa)

   a. 2022-4: Sales and Use Tax Exemption for Water Used for Commercial Production of Poultry

DEPARTMENT OF HEALTH, ARKANSAS STATE MEDICAL BOARD (Amy Embry; Matt Gilmore)

a. Rule No. 2.8: Requiring Minimum Standards for Establishing Provider/Patient Relationships

DEPARTMENT OF HUMAN SERVICES, DIVISION OF DEVELOPMENTAL DISABILITIES SERVICES (Melissa Weatherton; Patricia Gann)

a. CES Waiver Slot Increase

DEPARTMENT OF HUMAN SERVICES, DIVISION OF MEDICAL SERVICES (Melissa Weatherton, item a; Patricia Gann, items a-b; Mark White, Jay Hill, John Finkbeiner, items c-d)

a. HCBS and PASSE Waivers

b. Acute Crisis Units – Hospital Provider Manual

c. Living Choices Assisted Living Facility Waiver Renewal; LCAL 2-20

d. AR Choices in Homecare Renewal

DEPARTMENT OF HUMAN SERVICES, OFFICE OF CHIEF COUNSEL (Mark White; Brett Hays)

a. Declaratory Orders

DEPARTMENT OF LABOR AND LICENSING, DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING BOARDS AND COMMISSIONS, ARKANSAS TOWING AND RECOVERY BOARD (Miles Morgan; Steven Rogers)

a. Rules of the Arkansas Towing and Recovery Board

DEPARTMENT OF TRANSFORMATION AND SHARED SERVICES, BUILDING AUTHORITY DIVISION (Lauren Ballard; Jennifer Davis)

a. Building Authority Minimum Standards and Criteria

DEPARTMENT OF TRANSFORMATION AND SHARED SERVICES, OFFICE OF PERSONNEL MANAGEMENT (Lauren Ballard; Jennifer Elkins)

a. Unlawful Propagation of Divisive Concepts

3. The Subcommittee voted to not approve the following rule filed pursuant to Ark. Code Ann. § 10-3-309 on the grounds that the rule is inconsistent with state law:

   DEPARTMENT OF TRANSFORMATION AND SHARED SERVICES, OFFICE OF STATE PROCUREMENT (Lauren Ballard)

   a. Rules Governing Mandatory Procurement Training Program

4. The Subcommittee received agency updates on outstanding rulemaking pursuant to Act 595 of 2021.

5. The Subcommittee filed the September monthly written updates pursuant to Act 595 of 2021.

Respectfully submitted,

Senator Kim Hammer, Co-Chair

Representative Les Eaves, Co-Chair