UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* PHILIP WEISER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF COLORADO, *et al.*, *Defendants*.	Case No. 1:25-cv-02437-RMR Judge Regina M. Rodriguez

MOTION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF IN SUPPORT OF DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

The American Hospital Association, 340B Health, Colorado Hospital Association, and American Society of Health-System Pharmacists move for leave to file the attached *amici curiae* brief in support of Defendants' Response in Opposition to Plaintiff's Motion for Preliminary Injunction, ECF No. 33.[1]

Amici and their members are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. The discounts provided by the 340B program are essential to achieving this goal. *Amici* therefore have a strong interest in the success of Colorado's legislative efforts to protect the 340B program.

[1] Pursuant to Local Rule 7.1(a), Counsel for *amici curiae* emailed counsel for all parties regarding this Motion for Leave. Defendants consent to the Motion for Leave, and counsel for Plaintiff has not responded.

The **American Hospital Association** (AHA) represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations nationwide. AHA members are committed to helping ensure that healthcare is available to and affordable for all Americans. AHA promotes the interests of its members by participating as *amicus curiae* in cases with important and far-ranging consequences, including cases related to the 340B program.

340B Health is a national, not-for-profit organization founded in 1993 to advocate for 340B hospitals—a vital part of the nation's healthcare safety net. 340B Health represents over 1,600 public and private nonprofit hospitals and health systems participating in the 340B program.

Colorado Hospital Association (CHA) is the leading voice of the Colorado hospital and health system community. CHA serves as a trusted, credible, and reliable resource on health issues, hospital data, and trends for its members, media, policymakers and the general public. Through CHA, Colorado's hospitals and health systems work together in their shared commitment to improving health and health care in Colorado.

The **American Society of Health-System Pharmacists** (ASHP) is the largest association of pharmacy professionals in the United States. ASHP advocates and supports the professional practice of pharmacists in hospitals, health systems, ambulatory care clinics, and other settings spanning the full spectrum of medication use. For over 80 years, ASHP has championed innovation in pharmacy practice and has served as a steadfast advocate for members and patients.

* * *

Amici respectfully ask the Court for leave to file the attached *amici curiae* brief.

Dated: September 22, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 22, 2025, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

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UNITED STATES DISTRICT COURT
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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* PHILIP WEISER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF COLORADO, *et al.*, *Defendants*.	Case No. 1:25-cv-02437-RMR Judge Regina M. Rodriguez

BRIEF OF *AMICI CURIAE* THE AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, COLORADO HOSPITAL ASSOCIATION, AND AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS IN SUPPORT OF DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Over the past five years, 40 drug companies, including members of Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA"), have broken with decades of precedent and begun to refuse to ship drugs purchased by 340B hospitals to contract pharmacies. The federal government determined that this was unlawful and sought to require manufacturers to continue delivering these drugs to contract pharmacies on the same terms to which they delivered those drugs to 340B in-house hospital pharmacies.[1]

The drug companies (including PhRMA's members) fought that effort tooth and nail. In lawsuit after lawsuit, they argued that the federal government could not interfere with their contract pharmacy restrictions. At no point did the drug companies describe their contract pharmacy policies as price restrictions. Instead, they insisted that their policies were permissible because: (1) they were *delivery* restrictions, and (2) the 340B statute had absolutely nothing to say about contract pharmacies or *delivery*.[2] They won. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 460 (D.C. Cir. 2024) (Section 340B is "silent about delivery conditions"); *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health*

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[1] *See, e.g.*, Letter from Dep't of Health & Hum. Servs., Health Resources & Servs. Admin. Administrator C. Johnson to AbbVie, Inc. Vice Pres., U.S. Market Access C. Compisi (Oct. 17, 2022), https://www.hrsa.gov/sites/default/files/hrsa/opa/programintegrity/hrsa-letter-abbvie-covered-entities.pdf.

[2] *E.g.*, Novartis Opening Brief at 4, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299, Doc. 1949831 (D.C. Cir. June 8, 2022) ("Section 340B . . . is *silent* as to whether manufacturers must deliver those drugs to contract pharmacies.") (emphasis added); AstraZeneca Opening Br. at 4, *AstraZeneca Pharms. L.P. v. U.S. Dep't of Health & Hum. Servs.*, No. 22-01676 (3d Cir. July 21, 2022) ("Section 340B is 'silent' on the role of contract pharmacies under the program. That silence means the statute does not impose contract pharmacy obligations on manufacturers.").

& Hum. Servs., 58 F.4th 696, 703, 707 (3d Cir. 2023) (Section 340B's "text is silent about delivery" and "[l]egal duties do not spring from silence.").

Now comes the whiplash. Banking the wins of those drug companies, PhRMA now contends that Colorado's law, Senate Bill 25-071 ("S.B. 71"), requiring delivery to contract pharmacies regulates price, not delivery. And as part of that *volte-face*, PhRMA now insists that States cannot fill the federal statutory gap that other manufacturers have spent years fighting for in sister circuits. PhRMA's heads-I-win-tails-you-lose argument is as shameless as it is meritless.

This history is important—and not just because it exposes the hypocrisy in PhRMA's legal position. It also reminds the Court *why* Colorado chose to step into the federal statutory void. Colorado acted because drug companies and the other federal courts all but invited it to. S.B. 71 does only what the drug companies and the federal courts said the *federal* law did not do: regulate the delivery of 340B drugs. *See* Colo. Rev. Stat. § 6-29-101, et seq.

The primary issue here is whether Colorado, exercising its historic police power over health and safety, can fill the gap in the federal 340B statute and regulate the delivery of 340B drugs (purchased by 340B hospitals) to contract pharmacies. It can. Accordingly, PhRMA's claim fails.

First, S.B. 71 is not field preempted. PhRMA's arguments do not overcome "'the assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress.'" *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (internal citations omitted).

Congress did not create or occupy any field through its 340B legislation. *See PhRMA v. McClain*, 95 F.4th 1136, 1143 (8th Cir. 2024) *cert. denied*, 145 S. Ct. 768 (2024); *AbbVie v. Fitch*, No. 24-30675, 2025 WL 2630900 at *6-7 (5th Cir. Sept. 12, 2025); *AbbVie v. Skrmetti*, 2025 WL 1805271 at *13 (M.D. Tenn. June 30, 2025) (collecting cases). PhRMA's field preemption argument hinges on the false notion that 340B is "a comprehensive federal program" and "centralized control of that program" lies "exclusively within HHS." Complaint (Compl.) (ECF No. 1) ¶ 130. But comprehensiveness alone does not wrest traditional police power from the States. *E.g.*, *Hillsborough Cnty. v. Automated Med. Labs. Inc.*, 471 U.S. 707, 717 (1985); *English v. Gen. Elec. Co.*, 496 U.S. 72, 87 (1990); *N.Y. Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). And the 340B statute is silent as to delivery of 340B drugs and contract pharmacies, which is fatal to any field preemption claim, as numerous courts have found.[3]

Second, S.B. 71 is not conflict preempted. Colorado's law does not expand manufacturers' obligations under the 340B statute; it does not unlawfully limit access to claims data; it does not contravene federal enforcement authority; and it does not regulate 340B price, which continues to be set by federal law. *See AbbVie v. Fitch*, 2025 WL

[3] *E.g.*, *PhRMA v. McClain*, 95 F.4th at 1143–45; *AbbVie v. Fitch*, 2025 WL 2630900 at *6; *Novartis Pharms. Corp. v. Fitch*, 738 F. Supp. 3d 737, 747 (S.D. Miss. 2024); *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2024 WL 5345507, at *4–9 (S.D. Miss. Dec. 23, 2024); *Novartis Pharms. Corp. v. Bailey*, No. 2:24-cv-04131-MDH, 2025 WL 489881, at *2–4 (W.D. Mo. Feb. 13, 2025).

The only court to conclude that the drug manufacturers were likely to succeed on the merits of their preemption claim based its ruling on a fundamental misunderstanding of the 340B statute and program. *See PhRMA v. Morrissey*, 760 F. Supp. 3d 439 (S.D. W. Va. 2024). The *Morrisey* Court's conclusions have since been explicitly rejected by two other courts. *AstraZeneca Pharms. LP v. Fitch*, 766 F. Supp. 3d 657, 668 (S.D. Miss. 2024); *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271, at *16 (M.D. Tenn. June 30, 2025) ("This court, however, is not bound by *Morrisey* and is not persuaded by its reasoning.).

2630900 at *7-8. Colorado's law only affects *where* the 340B drugs (purchased by 340B hospitals) are shipped and stored. It is, in essence, a non-discrimination provision, allowing *Colorado* hospitals to choose where 340B drugs are to be shipped (a hospital pharmacy versus a contract pharmacy), rather than letting drug companies discriminate in favor of in-house hospital pharmacies.

At bottom, PhRMA's attack on S.B. 71 is an attack on federalism itself. PhRMA tries to transform federal statutory silence into a reason to displace traditional state authority. That is not the law, *see Paul v. Monts*, 906 F.2d 1468, 1475 n.8 (10th Cir. 1990) ("Congressional silence will not be presumed to mandate preemption."),[4] and PhRMA's claims seeking to undermine Colorado's lawful exercise of traditional state authority should be rejected.

ARGUMENT

I. PHRMA'S CLAIMS ARE MERITLESS.

A. S.B. 71 Is Not Preempted.

"The purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992) (citation omitted). In every preemption case, "and particularly in those in which Congress has 'legislated in a field which the States have traditionally occupied,'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485

[4] *See also, e.g.*, *Conway v. United States*, 997 F.3d 1198, 1211 (Fed. Cir. 2021) ("Congress' silence is powerful evidence that Congress did not intend to preempt state law fixing creditors' rights during insolvency." (cleaned up)); *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 985 (7th Cir. 2012) ("As we have noted, congressional and regulatory silence usually defeats a claim of preemption, not the other way around.") (emphasis in the original); *Iowa, Chi. & E. R.R. Corp. v. Washington Cnty.*, 384 F.3d 557, 561 (8th Cir. 2004); *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 6 (1st Cir. 1994) ("Pre-emption law, for example, cautions us against finding that a congressional act pre-empts a state law through silence." (internal citation omitted)).

(1996), courts "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 purpose of Congress," *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 432 (2002). That is "particularly" true in "matters of health," given "the historic primacy of state regulation" in that area. *Lohr*, 518 U.S. at 485. PhRMA cannot satisfy its "burden of overcoming th[e] presumption" against preemption. *PhRMA v. Walsh*, 538 U.S. 644, 662 (2003). This Court should reject each of PhRMA's various preemption theories—just as numerous other courts have done in substantially similar cases.[5]

1. Congress did not create or occupy a field in the 340B statute.

PhRMA's field-preemption theory both misapplies the relevant standard and mischaracterizes the 340B statute. Field preemption occurs only in narrow circumstances, "when federal law occupies a 'field' of regulation 'so comprehensively that it has left no room for supplementary state legislation.'" *Murphy v. NCAA*, 584 U.S. 453, 479 (2018) (citation omitted). Indeed, "[t]he subjects of modern social and regulatory legislation often by their very nature require intricate and complex responses from the Congress, but without Congress necessarily intending its enactment as the exclusive means of meeting the problem." *Dublino*, 413 U.S. at 415. Thus, the Supreme Court has "reject[ed] . . . the contention that pre-emption is to be inferred merely from the comprehensive character" of a federal statute. *Id.*; *see also AbbVie v. Fitch*, 2025 WL 2630900 at *6 ("Field preemption 'should not be inferred, however, merely because the

[5] *E.g.*, *PhRMA v. McClain*, 95 F.4th at 1143–45; *AbbVie v. Fitch*, 2025 WL 2630900 at *6-8; *PhRMA v. Murrill*, No. 6:23-cv-997, 2024 WL 4361597, at *8, (W.D. La. Sept. 30, 2024); *see also, e.g.*, *AbbVie v. Skrmetti*, 2025 WL 1805271, at *16; *Novartis v. Fitch*, 738 F. Supp. 3d at 747; *AstraZeneca v. Fitch*, 2024 WL 5345507, at *4–9; *Novartis v. Bailey*, 2025 WL 489881, at *2–4.

agency's regulations are comprehensive.'" (quoting *R.J. Reynolds Tobacco Co. v. Durham County*, 479 U.S. 130, 149 (1986)). Rather, a statute preempts an entire field only if it "reflect[s] a congressional decision to foreclose any state regulation in the area," and thus "confer[s] a federal right to be free from any other" requirements in the same field. *Murphy*, 584 U.S. at 479 (citation omitted).

PhRMA's field-preemption theory relies entirely on the (supposed) comprehensiveness of the 340B statute, its enforcement mechanisms, and its relationship to the Medicaid and Medicare programs. *See* Pl.'s Mot. for Prelim. Inj. ("Pl.'s MPI"), ECF No. 10 at 11-15; Compl. ¶ 131 (alleging that, in the 340B statute, "Congress designed a pervasive and integrated scheme of regulation"). But PhRMA is wrong to characterize the 340B statute as "comprehensive." Compl. ¶ 130. "Section 340B does not 'provide a full set of standards governing' discounted drugs for needy patients. Notably, it regulates neither the distribution of drugs to patients nor the role of pharmacies in this distribution." *AbbVie v. Fitch*, 2025 WL 2630900 at *6 (collecting sources) (internal citation omitted).

PhRMA knows this: many of its members (successfully) argued that the 340B statute is "silent about delivery conditions." *Novartis v. Johnson*, 102 F.4th at 460. For precisely that reason, the Fifth and Eighth Circuits, as well as numerous district courts, have concluded that the 340B statute is *not* comprehensive and rejected field preemption challenges to state contract pharmacy statutes materially identical to S.B. 71. *E.g., AbbVie v. Fitch*, 2025 WL 2630900 at *6 ("Congress chose not to regulate distribution to patients, indicating that it did not intend to occupy the entire field in this area."); *PhRMA v. McClain*, 95 F.4th at 1143 ("Congress's decision not to legislate the issue of pharmacy

distribution indicates that Section 340B is not intended to preempt the field."); *PhRMA v. Murrill*, 2024 WL 4361597, at *8; *AbbVie Inc. v. Skrmetti*, 2025 WL 1805271, at *13. This Court should follow this reasoning and reject PhRMA's field preemption theory here.

2. S.B. 71 does not conflict with the 340B statute.

The Court also should follow the growing chorus of appellate and district courts in rejecting PhRMA's conflict preemption theories. *E.g.*, *PhRMA v. McClain*, 95 F.4th at 1144-45; *AbbVie v. Fitch*, 2025 WL 2630900 at *7-8. A proper conflict preemption analysis requires parties to demonstrate that the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is a "high threshold," *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), and PhRMA comes nowhere close to meeting it.

The 340B statute was passed to help covered healthcare providers "reach[] more eligible patients and provid[e] more comprehensive services." *Final Rule, 340B Drug Pricing Program; ADR Regulation*, 89 Fed. Reg. 28,643, 28,643 (Apr. 19, 2024) (hereinafter, "ADR Rule"). Colorado's S.B. 71, in turn, enables 340B providers to continue to benefit from contract pharmacy arrangements and thereby offer expanded healthcare to their patients and "deliver[] [] life-saving drugs to eligible patients, including those who have limited access to transportation [or] live in remote or rural areas." Colo. Rev. Stat. § 6-29-102(1)(o). S.B. 71 therefore does not stand as an obstacle to the purposes of the 340B statute. "[I]t does the opposite: [S.B. 71] assists in fulfilling the purpose of 340B." *PhRMA v. McClain*, 95 F.4th at 1144-45; *see also CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 83 (1987).

More specifically, PhRMA proffers several ways in which S.B. 71 purportedly conflicts with the federal 340B statute. Each of PhRMA's arguments fails.

a. S.B. 71 does not expand the scope of 340B's federal requirements.

PhRMA's argument that S.B. 71 expands the scope of 340B's federal requirements, Pl.'s MPI at 16-19; Compl. ¶ 145, is "simply incorrect," *AbbVie v. Fitch*, 2025 WL 2630900 at *7 (rejecting similar argument against analogous state law). There are no federal requirements regarding delivery. *Novartis v. Johnson*, 102 F.4th at 46-62. The federal 340B statute dictates what price manufacturers must offer (the "ceiling price") and to whom (340B "covered entities"). 42 U.S.C. § 256b. S.B. 71 does not alter either requirement. *See AbbVie v. Fitch*, 2025 WL 2630900 at *7 (concluding that an analogous state statute merely "requires drug manufacturers to give custody of discounted drugs to contract pharmacies only insofar as they have partnered with covered entities to distribute the drugs to patients").

Instead, S.B. 71 sets forth Colorado's own requirements, with their own consequences. The law provides that a drug company may not limit "the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B covered entity, a pharmacy contracted with a 340B covered entity, or a location otherwise authorized by a 340B covered entity to receive and dispense 340B drugs." Colo. Rev. Stat. § 6-29-105(1)(a). Put another way, S.B. 71 bars drug companies from discriminating against Colorado 340B hospitals based on their chosen delivery location, taking the federal price as given at all times. It requires drug companies to allow covered entities to be treated like any other purchaser of drugs, with the same freedom to select where their drugs will be shipped. *See PhRMA v. Fitch*, 2024 WL 3277365, at *11 (S.D. Miss. July 1, 2024) ("Congress has not precluded Mississippi from enacting its own policy governing delivery of Section 340B drugs."). It

"does not set or enforce discount pricing." *McClain*, 95 F.4th at 1145; *see PhRMA v. Murrill*, 2024 WL 4361597, at *9 ("[D]iscounts are set by the federal government.").

Relying on the Third Circuit and D.C. Circuits' decisions in *Sanofi* and *Novartis v. Johnson*, PhRMA argues that S.B. 71 interferes with the conditions it was permitted to place on its "offer" to sell 340B drugs to 340B covered entities. Pl.'s MPI at 16-17 (citing *Sanofi,* 58 F.4th at 703-06 and *Novartis v. Johnson,* 102 F.4th at 460-64). But those decisions are not to the contrary. *PhRMA v. Murrill*, 2024 WL 4361597, at *8. While those courts permitted *drug companies* to place some reasonable conditions in the face of the federal law's "silence" about delivery, neither court addressed what the *States*, armed with their historic police powers over health and safety, may do to fill out those federal silences. *Sanofi Aventis*, 58 F.4th at 703; *Novartis v. Johnson,* 102 F.4th at 460.

b. S.B. 71 does not impede the federal audit and ADR process through minor restrictions on claims data.

PhRMA's complaint that S.B. 71 poses an obstacle to the federal administrative dispute resolution ("ADR") and audit process relies on a misleading description of the process. Pl.'s MPI at 19-21. Under the 340B statute, a manufacturer must audit a covered entity before initiating the statute's ADR process. 42 U.S.C. § 256b(d)(3)(B)(iv). PhRMA asserts that S.B. 71's data provision limits manufacturers' ability to collect the data necessary to get federal approval to conduct an audit under the 340B statute, preventing them from establishing "reasonable cause" to suspect that a covered entity is violating its statutory obligations. Pl.'s MPI at 20-21.

To the extent S.B. 71 prohibits upfront access to data, it does not interfere with the 340B statute's audit and ADR process. The threshold that a drug manufacturer must meet when seeking HRSA's approval to audit a 340B entity is "*not overly burdensome*" and

does not "present *any barriers* to a manufacturer's ability to perform an audit of a covered entity." ADR Rule, 89 Fed. Reg. at 28,646 (emphasis added). The standard for audit approval—"reasonable cause"—is satisfied whenever "a reasonable person *could* believe that a covered entity *may have* violated [certain provisions of the 340B statute]." HRSA, *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). This standard can be met in various ways without claims data, including by pointing to "[s]ignificant changes in quantities of specific drugs ordered by a covered entity," or by citing "complaints from patients/other manufacturers about activities of a covered entity[.]" *Id.* at 65,406; *Or. Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *5 (D.D.C. June 17, 2025); *see, e.g.*, Ex. A, Decl. of Chantelle V. Britton, HRSA Office of Pharmacy Affairs, at ¶ 9 (Dec. 19, 2024) (noting HRSA's approval of a manufacturer's audit request that was "based on a stark increase in [a provider's] utilization of the 340B program," not any data suggesting issues with specific claims).[6]

In addition, the 340B statute contemplates that manufacturers will collect specific evidence of covered entities' potential statutory violations *through an audit*—not as a prerequisite to conducting one. The statute expressly addresses a manufacturer's access to "the records of [a 340B] entity that directly pertain to the entity's compliance with [the 340B statute] with respect to the drugs of the manufacturer." 42 U.S.C. § 256b(a)(5)(C). It provides that a manufacturer can access those records *via an* "*audit*." *Id.* (emphasis

[6] As the Director of HRSA's Office of Pharmacy Affairs ("OPA"), Ms. Britton "oversee[s] the OPA staff that reviews requests by drugmakers that participate in the 340B Program to audit covered entities." Ex. A at ¶ 2. HRSA submitted Ms. Britton's declaration in *University of Washington Med. Ctr. v. Becerra,* Case No. 1:24-cv-2998-RC (D.D.C) which is associated connection with *Or. Health & Sci. Univ. v. Engels*, Case No. 1:24-cv-2184-RC (D.D.C.).

added). HRSA guidance similarly explains that, in the ADR process, manufacturers can establish covered entity violations because they "have the ability to gather needed information *through the audits*." ADR Rule, 89 Fed. Reg. at 28,652 (emphasis added). In contrast, HRSA's decision to *approve* a manufacturer audit is "preliminary [in] nature," *Or. Health & Sci. Univ. v. Engels*, 2025 WL 1707630, at *5 (D.D.C. June 17, 2025), and does not require that the manufacturer be able to prove any suspected violations using data regarding specific claims. PhRMA's concern that its members need claims data *before* any audit ignores the statutory scheme.

In fact, manufacturers seldom ask to conduct audits, and even when they do, they often fail to follow through with them. *See* Ex. A, Decl. of Chantelle Britton at ¶ 15 (noting that, "over the past decade-plus," HRSA approved 37 manufacturer audit requests, but only 18 audits were conducted).[7] And more fundamentally, *amici* are not aware of a single instance when HRSA has *ever* required, as a condition of authorizing a manufacturer audit, the sort of data that PhRMA now claims its members must be allowed to demand from covered entities. Put simply, S.B. 71 is not an obstacle to pursuing the audit and ADR process under the 340B statute, and the Court should reject PhRMA's audit-based preemption theory.[8]

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[7] In contrast, HRSA itself audits approximately 200 covered entities each year for compliance with their 340B obligations. *See* U.S. Gov't Accountability Office, *Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance With 340B Requirements* at 11 (Dec. 2020), https://www.gao.gov/assets/gao-21-107.pdf. This includes "targeted" audits of covered entities when HRSA receives "information from stakeholders such as drug manufacturers about potential noncompliance." *Id.* at 11 n.22.

[8] PhRMA additionally argues that under guidance from the Centers from Medicare and Medicaid (CMS), claims data is necessary to avoid providing the "maximum fair price" on drugs selected under the Medicare Drug Price Negotiation Program, established under the Inflation Reduction Act (IRA) if those drugs are also 340B-eligible. Pl.'s MPI at 21.

c. S.B. 71 does not interfere with 340B's remedial and enforcement regime.

Finally, PhRMA contends that S.B. 71 "impermissibly attempts to permit private suits to enforce 340B" and creates a state enforcement regime that "conflicts with Congress's chosen scheme of exclusive federal oversight for 340B." Compl. ¶ 151-52; Pl.'s MPI at 22-23. But S.B. 71's "enforcement scheme does not conflict with Section 340B's enforcement scheme." *AbbVie v. Fitch*, 2025 WL 2630900 at *8 (analyzing analogous state statute). The statute does not authorize private parties or Colorado to bring suits to "enforce 340B." Compl. ¶ 151; Pl.'s MPI at 22. Instead, S.B. 71 strictly provides for the enforcement of *its own* requirements—not the requirements of the 340B statute. *See* Colo. Rev. Stat. § 6-29-105(3).

As the Eighth Circuit explained with respect to a similar Arkansas statute:

> Act 1103 ensures that covered entities can utilize contract pharmacies for their distribution needs and authorizes the Arkansas Insurance Division to exact penalties and equitable relief if manufacturers deny 340B drugs to covered entities' contract pharmacies. Ark. Code Ann. § 23-92-604(c). The 340B Program, on the other hand, addresses discount pricing. ***Therefore, HHS has jurisdiction over different disputes***: disputes between covered entities and manufacturers regarding pricing, overcharges, refunds, and diversion of 340B drugs to those who do not qualify for discounted drugs.

PhRMA v. McClain, 95 F.4th at 1144 (emphasis added); *see also AbbVie v. Fitch*, 2025 WL 2630900 at *8 (finding an analogous Mississippi statute "does not intrude upon [federal] authority because" it only "imposes penalties" for interference "with the distribution of Section 340B drugs," "not . . . for violations of Section 340B"). Because, like the Arkansas statute, the requirements that can be enforced under S.B. 71 are

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However, guidance related to an *entirely separate statute* is plainly irrelevant to whether S.B. 71 conflicts with the *340B statute*.

different from the 340B program requirements, it does not conflict with the 340B program's enforcement regime.

PhRMA argues that S.B. 71 requires Colorado to adjudicate "multiple questions of federal law." *See* Pl.'s MPI at 23. Not so. The Colorado statute regulates the delivery of a 340B drug that has been purchased by a 340B hospital. Again, the question in any state action to enforce S.B. 71 would be whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy. If a manufacturer wants to argue that a drug was dispensed to a non-340B patient or that the company has been forced to pay a duplicate discount, for instance, that is an argument for HRSA—not the State.

And there is nothing improper about a state statute defining its reach by reference to federal law (and then imposing its own requirements) or a state statute whose "regulatory object" is a federal program. *See Whiting*, 563 U.S. at 607-08 (rejecting preemption challenge to a state statute under which employers had to check their employees' *federal* immigration status using a specified *federal* database). Nor is it unusual for a state statute to expressly reference a federal program or statute in defining its reach. *See, e.g.*, Colo. Rev. Stat. Ann. § 11-59-103(8)(e) (incorporating definition of "business development company" from the "federal 'Investment Company Act of 1940'").

PhRMA's mentions of diversion of drugs to non-eligible patients is also irrelevant to its challenge to S.B. 71. As discussed, the question in any state action arising under the Colorado statute is whether the manufacturer refused to deliver a drug purchased by a 340B hospital to a contract pharmacy. So, the issue of diversion, which relates to dispensing drugs to a non-340B patient, is outside the scope of the Colorado law. And this makes sense because if diversion were an issue, the federal 340B statute requires

that HRSA determine whether the 340B drug purchase complied with federal law *after the fact* either through an audit or in the *post hoc* ADR process, following a manufacturer audit. 42 U.S.C. §§ 256b(d)(2)(B)(iv) & (3). As such, S.B. 71 and the federal 340B statute enforce different things and therefore do not raise the possibility of conflicting enforcement decisions.[9]

CONCLUSION

340B savings allow hospitals to care for Colorado's most vulnerable patients in a variety of ways. For example, Intermountain Health uses 340B dollars to provide subsidized health services, including infusion services for cancer care, dialysis for kidney failure, and neonatal intensive care. Lincoln Health administers a patient savings initiative that fully transfers 340B drug discounts to patients, which enabled its patients to save over $800,000 collectively in 2024.

Nevertheless, PhRMA spends page after page maligning the 340B Program and the covered entities that rely on it. But this is not how the Supreme Court has viewed the program. As Justice Kavanaugh wrote for a unanimous Supreme Court just a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). Sharing this view, the Colorado legislature—with an unbiased interest

[9] PhRMA relies on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), Pl.'s MPI at 22-23, which does not address preemption and is inapposite, *see PhRMA v. Murrill*, 2024 WL 4361597, at *7. The *Astra* Court's hesitance to allow "potentially thousands of" private parties to sue to correct "errors in manufacturers' price calculations" has no bearing on whether *States* can fill gaps in federal law regarding the delivery of 340B drugs. *Astra,* 563 U.S. at 114. Indeed, the only mention of preemption in *Astra* is in a footnote concerning a different federal program. *Id.* at 120 n.5.

in protecting its citizens, hospitals, and pharmacies—rejected the drug companies' efforts to denigrate the 340B Program and those who rely on it by enacting S.B. 71.

This Court should similarly reject PhRMA's efforts to defeat S.B. 71 in the judicial branch. For all of the reasons stated above, its legal claims lack merit. Accordingly, PhRMA's Motion should be denied.

Dated: September 22, 2025

Respectfully submitted,

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I certify that on September 22, 2025, I caused the foregoing to be served via the Court's ECF filing system on all registered counsel of record.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* PHILIP WEISER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF COLORADO, *et al.*, *Defendants*.	Case No. 1:25-cv-02437-RMR Judge Regina M. Rodriguez

CORPORATE DISCLOSURE STATEMENT OF
AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Pursuant to Federal Rule of Civil Procedure 7.1, *amicus curiae* American Society of Health-System Pharmacists hereby states that it is a non-profit organization with no parent corporation and no stock owned by any publicly held corporation.

Dated: September 22, 2025

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UNITED STATES DISTRICT COURT
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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* PHILIP WEISER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF COLORADO, *et al.*, *Defendants*.	Case No. 1:25-cv-02437-RMR Judge Regina M. Rodriguez

CORPORATE DISCLOSURE STATEMENT OF 340B HEALTH

Pursuant to Federal Rule of Civil Procedure 7.1, *amicus curiae* 340B Health hereby states that it is a non-profit organization with no parent corporation and no stock owned by any publicly held corporation.

Dated: September 22, 2025

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UNITED STATES DISTRICT COURT
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PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* PHILIP WEISER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF COLORADO, *et al.*, *Defendants*.	Case No. 1:25-cv-02437-RMR Judge Regina M. Rodriguez

CORPORATE DISCLOSURE STATEMENT OF
THE AMERICAN HOSPITAL ASSOCIATION

Pursuant to Federal Rule of Civil Procedure 7.1, *amicus curiae* the American Hospital Association hereby states that it is a non-profit organization with no parent corporation and no stock owned by any publicly held corporation.

Dated: September 22, 2025

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, *v.* PHILIP WEISER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF COLORADO, *et al.*, *Defendants*.	Case No. 1:25-cv-02437-RMR Judge Regina M. Rodriguez

CORPORATE DISCLOSURE STATEMENT OF
COLORADO HOSPITAL ASSOCIATION

Pursuant to Federal Rule of Civil Procedure 7.1, *amicus curiae* Colorado Hospital Association hereby states that it is a non-profit organization with no parent corporation and no stock owned by any publicly held corporation.

Dated: September 22, 2025

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