

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE**

MARY HITCHCOCK MEMORIAL HOSPITAL,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 1:26-cv-00616-SM-TSM

**MOTION OF AMERICAN HOSPITAL ASSOCIATION, 340B HEALTH, AND NEW
HAMPSHIRE HOSPITAL ASSOCIATION TO FILE BRIEF AS *AMICI CURIAE* IN
SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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NOW COMES the American Hospital Association, 340B Health, and New Hampshire Hospital Association, by and through their attorneys, McLane Middleton, Professional Association, and Zuckerman Spaeder, LLP, and respectfully request this Honorable Court grant leave to file an amicus brief supporting Plaintiff's Motion for Preliminary Injunction. In support thereof, the following is stated:

1. For the reasons explained in the accompanying Memorandum, proposed *Amici Curiae* the American Hospital Association, 340B Health, and the New Hampshire Hospital Association respectfully move this Court for leave to file an amicus brief supporting Plaintiff Mary Hitchcock Memorial Hospital's Motion for a preliminary injunction.
2. The proposed amicus brief is attached as **Exhibit 1**.
3. Plaintiff consents to this Motion, and Defendant opposes the Motion.

Dated: October 1, 2026

Respectfully submitted,

/s/ Michael A. Delaney

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion of American Hospital Association, 340B Health, and New Hampshire Hospital Association to File Brief as *Amici Curiae* in Support of Plaintiff's Motion for Preliminary Injunction was filed electronically on this 1st day of October 2026, and will, therefore, be served electronically upon counsel for the parties.

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INTERESTS OF *AMICI CURIAE*

Proposed *Amici* include three hospital associations with members in New Hampshire that are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. *Amici* and their members benefit from the statutory discounts to which they are entitled under the federal 340B statute and would be greatly harmed if Defendant Eli Lilly & Co (Lilly) were permitted to violate state unfair trade practices laws through the imposition of its onerous claims data policy.

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 for their members, 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.

The **New Hampshire Hospital Association** represents all 26 acute care and 5 specialty hospitals in New Hampshire. NHHA provides leadership through advocacy, education, and information in support of its member providers and health systems as they strive to improve the health of the individuals and communities they serve.

INTRODUCTION

Plaintiff Mary Hitchcock Memorial Hospital (MHMH) seeks to prevent Lilly from imposing onerous claims data policy in violation of state laws meant to protect consumers from unfair trade practices. *Amici* submit this brief to explain that (1) MHMH is likely to succeed on the merits of its claims because (a) the federal 340B statute does not preempt such state law claims

and (b) *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011) does not bar MHMH’s claims, and (2) MHMH (and other covered entities) will suffer irreparable harm absent injunctive relief because Lilly’s claims data policy forces it to choose between incurring onerous administrative burdens or purchasing drugs at full price—both of which will compromise its ability to provide essential care to patients.

ARGUMENT

I. MHMH IS LIKELY TO SUCCEED ON THE MERITS OF ITS CLAIMS.

A. MHMH’s Claims Are Not Preempted By 340B.

Lilly argues that MHMH’s claims are preempted by the federal 340B statute, citing principles of field preemption, conflict preemption, and intergovernmental immunity, among other things. But Lilly’s field and conflict preemption theories are dead wrong, and Lilly’s intergovernmental immunity argument stretches that doctrine beyond recognition. Numerous courts have rejected all three arguments. *PhRMA v. Frey*, No. 1:25-cv-00469-JCN, 2026 WL 184504, at *7–15 (D. Me. Jan. 23, 2026); *AbbVie Inc. v. Jackley*, Nos. 3:25-cv-03006-RAL, 3:25-cv-03021-RAL, 4:25-cv-04156-RAL, 2026 WL 2280929, at *13–20, 22–25 (D.S.D. Aug. 7, 2026); *Novartis Pharms. Corp. v. Brown*, No. 3:26-cv-05302-DGE, 2026 WL 1660347, at *9–21 (W.D. Wash. June 9, 2026); *PhRMA v. Torrez*, No. 25-cv-1225, 2026 WL 1752214, at *10 (D.N.M. May 26, 2026), *appeal filed*, No. 26-2097 (10th Cir.). Notably, these cases involved state laws designed to prevent drug companies from using onerous claims data policies to reduce access to 340B medications. That is exactly what Lilly’s policy does here.

1. Federal Law Does Not Occupy the Field.

Lilly’s field preemption theories both misapply the relevant standard and mischaracterize MHMH’s state law claims. Similar arguments have been rejected by nearly every Court to consider them, including the Fifth and Eighth Circuits, in the context of manufacturer suits challenging state

laws governing delivery of 340B drugs to covered entities’ contract pharmacies. *See, e.g., AbbVie v. Murrill*, 180 F.4th 747, 758–62 (5th Cir. 2026); *PhRMA v. McClain*, 95 F.4th 1136, 1144 (8th Cir. 2024); *AbbVie Inc. v. Fitch*, 152 F.4th 635, 646 (5th Cir. 2025); *Novartis Pharms. Corp. v. Hanaway*, 180 F.4th 1097, 1113 (8th Cir. 2026), *en banc review denied*, --- F.4th ----, 2026 WL 2729618 (8th Cir. Sept. 16, 2026). This Court should do the same.

Courts do not infer field preemption of a State statute in an area traditionally within the scope of States’ police powers. *See, e.g., English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Instead, field preemption is found only in rare instances, “when federal law occupies a ‘field’ of regulation ‘so comprehensively that it has left no room for supplementary state legislation.’” *Murphy v. NCAA*, 138 S. Ct. 1461, 1480 (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.” *N.Y. State Dep’t of Soc. Servs. v. Dublino*, 413 U.S. 405, 415 (1973). Thus, the Supreme Court has rejected “the contention that pre-emption is to be inferred merely from the comprehensive character” of federal provisions. *Id.*; *see also English*, 496 U.S. at 87. With the 340B program, “a detailed statutory scheme was both likely and appropriate, completely apart from any questions of pre-emptive intent.” *Dublino*, 413 U.S. at 415. Ignoring precedent, Lilly relies on what it describes as the “pervasive” and “comprehensive” character of the federal scheme to support its field preemption argument. Lilly Opp’n 29. But Lilly fails to cite authority for its assertions about Congress’s *intent* to create or occupy this purported 340B “field.”

Lilly also suggests that MHMH’s claims threaten 340B’s “exclusive federal enforcement” regime because they “arise entirely” from the 340B program. Lilly Opp’n 30. This argument reflects a misunderstanding of MHMH’s claims. MHMH seeks to prevent Lilly from

discriminating against safety-net providers by imposing onerous conditions on the sales of its drugs to protect consumers—not to enforce the terms of the federal 340B statute. MHMH’s ability to succeed in its claims is wholly separate from the question of whether Lilly’s claims data policy violates 340B, and MHMH does not seek to prove that Lilly’s conduct runs afoul of the federal law. Accordingly, MHMH’s claims do not in any way seek to enforce the federal requirements of 340B.

2. *MHMH’s Claims Do Not Conflict with the 340B Statute.*

Lilly next argues that MHMH’s claims are preempted because they conflict with the federal 340B statute. But Lilly fails to identify any actual conflict between MHMH’s state law claims and the 340B statute. The Fifth Circuit has persuasively explained that, under the Supreme Court’s decision in *Arizona*, 567 U.S. 387, the 340B statute does not preempt the application of state laws to 340B because the federal statute “does not ‘provide a full set of standards governing’ discounted drugs for needy patients.” *AbbVie v. Fitch*, 152 F.4th at 646 (quoting *Arizona v. United States*, 567 U.S. 387, 401 (2012)). This Court should join the chorus of courts that have rejected Lilly’s conflict preemption argument (in the state contract pharmacy law context). *E.g.*, *AbbVie v. Murrill*, 180 F.4th at 760–61; *Novartis v. Hanaway*, 180 F.4th at 1113; *PhRMA v. McClain*, 95 F.4th at 1144–45; *AbbVie v. Fitch*, 152 F.4th at 647–48; *AstraZeneca v. Weiser*, No. 25-cv-02685-PAB-STV, 2026 WL 2568299, at *7–9 (D. Colo. Aug. 31, 2026). Lilly cannot meet the “high threshold,” *Chamber of Com. of U.S. v. Whiting*, 563 U.S. 582, 607 (2011), for showing that MHMH’s claims “stand[] 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).¹

¹ *Novartis v. Hanaway*, 180 F.4th at 1113; *AbbVie v. Murrill*, 180 F.4th at 760–62; *AbbVie v. Fitch*, 152 F.4th at 647–48; *PhRMA v. McClain*, 95 F.4th at 1144; *AstraZeneca Pharms. LP v. Frey*, No. 1:25-cv-495-JCN, 2026 WL 2145194, at *5–13 (D. Me. July 27, 2026); *PhRMA v. Frey*, 2026 WL 184504, at *9–15; *Novartis Pharms. Corp. v. Frey*, Nos. 1:25-cv-407-JCN, 1:25-cv-416-JCN, 2025 WL 2813787, at *8–12 (D. Me. Sept. 23, 2025).

First, rather than posing any obstacle to the aims of the federal 340B statute, MHMH’s claims advance them. *See AbbVie v. Murrill*, 180 F.4th at 762 (explaining that the Louisiana contract pharmacy law statute and the 340B statute work “in tandem to advance Congress’s central aim: ensuring that ‘manufacturers participating in Medicaid . . . offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor.’”). The federal 340B statute was enacted to help covered healthcare providers “‘reach[] more eligible patients and provid[e] more comprehensive services.’” *Am. Hosp. Ass’n v. Hargan*, 289 F. Supp. 3d 45, 47 (D.D.C. 2017) (quoting H.R. Rep. No. 102–384(II), at 12 (1992)). If successful, MHMH’s claims would enable 340B providers to continue to provide essential healthcare to their patients without incurring the prohibitive administrative burdens of Lilly’s claims data policy, thereby “assist[ing] in fulfilling the purpose of 340B.” *PhRMA v. McClain*, 95 F.4th at 1144–45.

Second, to support its conflict preemption argument, Lilly relies on *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001), a wholly inapposite case that undermines—rather than supports—its position. In that case, the Supreme Court found that the Federal Food, Drug, and Cosmetic Act preempted state law claims styled as fraud on the U.S. Food and Drug Administration. *Buckman*, 531 U.S. at 352. When analyzing those state law fraud-on-the-federal-agency claims, *Buckman* found that the laws implicated a unique federal interest. The Court explained: “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied’”; the state law fraud-on-the-agency claim would regulate something that is “‘inherently federal in character.’” 531 U.S. at 347 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)); *see U.S. Airways v. O’Donnell*, 627 F.3d 1318, 1325 (10th Cir. 2010) (citing *Buckman* for the proposition that the presumption against preemption does not apply in a case involving a field “long [] dominated by federal interests”); *Chamber of Commerce v. Whiting*, 563

U.S. 582, 604 (2011) (plurality opinion) (rejecting *Buckman*-based preemption argument because the state statute at issue did not involve “an area of dominant federal concern”).

As the Supreme Court later explained in *Wyeth v. Levine*, “*Buckman Co. v. Plaintiffs’ Legal Comm.* . . . involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety as matters to which the presumption [against preemption] *does* apply.” 555 U.S. 555, 565 n.3 (2009). Like *Wyeth*, where the Court held that the Federal Food, Drug and Cosmetic Act does not preempt state failure to warn claims, this case involves matters of health and safety—issues that fall squarely within a state’s historic police powers. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

Third, to support its argument that a prohibition on its claims data policy would pose an obstacle to the Health Resources and Services Administration’s (HRSA’s) audit process, Lilly relies on a misleading description of that process. *See Novartis v. Frey*, 2025 WL 2813787, at *12 (rejecting the drug manufacturers’ claims that a state law prohibition on claims data requirements conflicts with 340B). Lilly suggests that a ruling barring it from unilaterally demanding claims data from covered entities would interfere with its ability to access the audit procedures of the 340B program. Lilly Opp’n 27–28. But claims data has never been required to meet HRSA’s standard for authorizing an audit (and Lilly does not give a single example of a time that HRSA has denied a manufacturer’s audit request for failure to include claims data, and *Amici* are aware of none). This standard 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) (emphasis added). It can be met 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*, Nos. 24-2184 (RC), 24-2187 (RC), 24-2268 (RC), 24-2563 (RC), 24-2998 (RC), 2025 WL 1707630, at *5 (D.D.C. June 17, 2025). Drug companies can (and do) make this showing without claims data.

What’s more, the 340B statute contemplates that manufacturers will collect specific evidence of covered entities’ potential statutory violations *through* an audit. The statute provides that a manufacturer can access records related to an entity’s compliance *via* an “audit.” 42 U.S.C. § 256b(a)(5)(C). HRSA guidance similarly explains that, in the Alternative Dispute Resolution process, manufacturers can establish covered entity violations because they “have the ability to gather needed information *through the audits*.” ADR Rule, 89 Fed. Reg. 28,643, 28,652 (emphasis added). In contrast, HRSA’s decision to *approve* a manufacturer audit is “preliminary [in] nature,” *Or. Health & Sci. Univ.*, 2025 WL 1707630, at *5. HRSA has never required that manufacturers, *before* conducting an audit, must be able to prove violations using data regarding specific claims. Lilly’s argument to the contrary puts the cart before the horse.

3. *MHMH’s Claims Do Not Discriminate Against Participants in a Federal Program.*

Lilly further contends that MHMH’s claims violate the intergovernmental immunity doctrine because they seek to impose requirements on it based on its participation in the federal 340B Program. Lilly Opp’n 30–31. But Lilly’s breathtakingly broad position is not the law. The intergovernmental immunity doctrine prohibits state laws that “discriminate[] against *the Federal Government or its contractors* if it singles them out for less favorable treatment, or if it regulates them unfavorably on some basis related to their governmental status.” *United States v. Washington*, 596 U.S. 832, 839 (2022) (emphasis added) (cleaned up). Every court to address “intergovernmental immunity” in the context of section 340B has rejected the argument that manufacturers are federal government contractors, correctly finding that the imposition of state

law requirements on drug manufacturers that participate in the 340B program “do not in any way apply to the United States or any of its agencies or employees.” *AstraZeneca Pharms. LP v. Lopez*, Civil No. 25-00369 MWJS-WRP, 2026 WL 497141, at *15 (D. Haw. Feb. 23, 2026).² The reason for this finding is clear: “Manufacturers opting into the 340B program are quite simply not federal contractors.” *PhRMA v. Torrez*, 2026 WL 1752214, at *10.

MHMH’s claims also do not discriminate against the “operations of the Federal Government.” *Washington*, 596 U.S. at 838 (emphasis added). Nor do they regulate any government contractors or other entities doing work for the federal government or assisting with federal government operations. *See PhRMA v. Frey*, 2026 WL 184504, at *6–7. Indeed, “[d]rug manufacturers participating in the 340B program . . . do not agree to perform any function of the federal government or provide any goods or services to the federal government.” *Id.* at *6. Instead, they “agree to provide discounts in the marketplace to certain other private entities.” *Id.* Drug companies therefore “do not fall within any of the recognized categories of entities with whom the government ‘deals’ for purposes of intergovernmental immunity, such as employees, contract workers, suppliers, or instrumentalities.” *Id.*

Lilly tries to dress up its participation in the 340B program in the cloak of a federal contractor, but the Court should reject that mischaracterization (as has every other court to consider it). Pharmaceutical Pricing Agreements (PPAs) do not transform mere program participants into federal contractors that *perform work for* the government. The “contract” merely sets forth the terms of the statute and governs manufacturers’ participation in a federal program as regulated

² *See also PhRMA v. Frey*, 2026 WL 184504, at *6; *Novartis v. Brown*, 2026 WL 1660347, at *9; *PhRMA v. Torrez*, 2026 WL 1752214, at *10; *AbbVie Inc. v. Murrill*, 166 F.4th 528, 544 (5th Cir. 2026), *opinion withdrawn and superseded on reh’g*, No. 24-30645, 2026 WL 1947948, at *12 (5th Cir. July 6, 2026); *AstraZeneca v. Frey*, 2026 WL 2145194; *AbbVie Inc. v. Jackley*, 2026 WL 2280929; *AstraZeneca Pharms. LP v. Fitch*, No. 1:24-cv-196-LG-BWR, 2026 WL 2455376, at *8 (S.D. Miss. Aug. 21, 2026); *AbbVie Inc. v. Wrigley*, 832 F. Supp. 3d 920, 938 (D.N.D. 2026) (concluding that the intergovernmental immunity doctrine did not apply in the context of a suit challenging North Dakota’s contract pharmacy statute because “manufacturers are not agents of the federal government”).

entities. As *Frey* explained, PPAs do not “confer[]” “contractor status with the federal government.” 2026 WL 184504, at *6. And critically, even if Plaintiffs qualified as government contractors, their contracts are silent with respect to claims data.

B. *Astra* Does Not Bar MHMH’s Claims.

Lilly’s reliance on *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110 (2011), is misplaced. Contrary to Lilly’s contention, *Astra* addressed only whether covered entities could use a third-party beneficiary theory to enforce the 340B statute’s federal requirements. Nothing about *Astra* displaced the Supreme Court’s well-established principle that “the mere existence of a federal regulatory or enforcement scheme . . . does not by itself imply pre-emption of state remedies.” *English*, 496 U.S. at 87. The *Astra* Court’s hesitance to allow “potentially thousands of covered entities” to sue to correct “errors in manufacturers’ price calculations” has no bearing on whether state unfair trade practices and consumer protection laws apply to drug companies participating in the federal 340B program (it does). *See Astra*, 563 U.S. at 114.

This case is different from *Astra* in two important ways. *First*, Lilly does not dispute (nor could it) that MHMH has pleaded valid state statutory and common law causes of action. By contrast, in *Astra*, the plaintiffs sought to sue as third-party beneficiaries to the defendant drug companies’ PPAs that they had entered into with the federal government to participate in the 340B program. As described above, PPAs are not contracts in the traditional sense but rather the form agreements by which manufacturers opt into the 340B program. *Astra*, 563 U.S. at 113. Unlike the independent state law causes of action forming the basis of MHMH’s preliminary injunction motion, PPAs create no enforceable rights and do not provide a cause of action. *Id.* The Supreme Court reasoned that “[a] third-party suit to enforce an HHS-drug manufacturer agreement . . . is in essence a suit to enforce the statute itself.” *Id.* at 118. Not so here.

Second, unlike in *Astra*, MHMH’s claims do not rise and fall with the finding that Lilly violated its obligations under the federal 340B statute. In *Astra*, the plaintiff covered entity “based its suit on allegations that the manufacturers charged more than the § 340B ceiling price.” *Id.* at 118–19. In other words, the *Astra* plaintiff’s ability to succeed on the merits was tied directly to proving that the nine pharmaceutical company defendants calculated the 340B discount in a way that violated *federal law*. Here, MHMH could prevail in its causes of action alleging violations of state laws, namely unfair trade practices and consumer protection laws without regard to whether Lilly complied with the 340B statute. MHMH does not bring suit for Lilly’s failure to provide 340B discounts; it challenges Lilly’s claims data policy, which runs afoul of *state* unfair trade practices and consumer protection law. This could not be adjudicated through ADR.

Mosaic Health, Inc. v. Sanofi-Aventis U.S., LLC is instructive in this regard. 156 F.4th 68 (2d Cir. 2025). There, the Second Circuit rejected the defendant manufacturer’s attempt to invoke *Astra* as a bar to the plaintiff covered entities’ federal antitrust lawsuit claiming violations of the Sherman Act. Finding that the plaintiffs’ operative complaint “is ‘agnostic as to [the] question’ of whether Defendants violated Section 340B,” and that “[t]he instant case does not turn on the meaning of the Section 340B statute nor on a determination from this Court as to whether Defendants violated Section 340B[,]” the court concluded that *Astra* did not prevent the plaintiffs from moving forward with their suit. *Id.* at 78–79. The court further found that, in contrast to *Astra*, the plaintiffs’ Sherman Act claims did not in any way interfere with the administrative dispute resolution mechanism of the 340B statute because “Congress vested authority in HHS to oversee compliance with the Section 340B Drug Discount Program and enforce the ceiling price contracts, not to police antitrust violations.” *Id.* at 79. As in *Mosaic*, MHMH seeks to enforce wholly distinct

state law obligations, and the success of its suit is agnostic as to whether Lilly's conduct violates 340B.

For similar reasons, Lilly's attempt to distinguish the Ninth Circuit's decision in *U.S. ex rel. Adventist Health Sys. of W. v. AbbVie Inc.*, 169 F.4th 1137, 1141 (9th Cir. 2026), is as misleading as it is unavailing. Lilly insists that *Adventist Health System* involves False Claims Act claims to "recover money owed to the *federal government* for the federal government's *own* purported claims under federal law," whereas "MHMH seeks relief solely for itself." Lilly Opp'n 24 (emphasis in original). But the Ninth Circuit's decision in no way whatsoever turned on who would obtain relief. Instead, the Ninth Circuit explained that "Adventist's action is not 'in essence' a suit to enforce Section 340B." *Adventist Health Sys.*, 169 F.4th at 1143 (citing *Astra*, 563 U.S. at 118). "Unlike plaintiff in *Astra*, Adventist brings a prototypical FCA action that does not assert that defendants are liable merely because of a direct violation of Section 340B." *Id.* So too here.

In short, as both the Ninth and Second Circuit have recently held, *Astra* has no bearing on cases where, as here, a plaintiff's claim does not turn on violations of the 340B statute itself.

II. MHMH AND OTHER COVERED ENTITIES WILL SUFFER IRREPARABLE HARM ABSENT INJUNCTIVE RELIEF.

Lilly's unlawful claims data policy forces covered entities to either shoulder onerous administrative burdens or forego statutory discounts that enable them to provide life-saving care to patients in need. Either option would severely harm MHMH and *Amici*'s members in New Hampshire.

Contrary to Lilly's unsupported assertions, Lilly Opp'n 16–20, forcing covered entities to comply with its draconian claims data policy would impose massive burdens on cash-strapped safety-net providers often operating on razor-thin margins. Critically, Lilly's policy requires 340B hospitals to compile and submit a vast range of new data for drugs dispensed at in-house

pharmacies or risk losing access to 340B discounts. For example, Lilly’s notice stated that “[f]ailure to provide timely, complete, and accurate data for all products dispensed at 340B ceiling prices may result in loss of access to pricing until such time as the outstanding data is provided.” In effect, these drug companies are now telling hospitals that treat America’s most vulnerable patients that they must hand over an unprecedented amount of data or not receive the discounts they are owed by federal statute.

The scope and volume of data that Lilly requires goes well beyond standard business information. Indeed, requiring 340B hospitals to submit both pharmacy and medical claims³ is unprecedented—and unprecedently onerous. This is because data for in-house dispenses are often spread across multiple disparate data systems. Reconciling and aligning those systems would create significant costs for covered entities, requiring them to divert vital dollars away from patient care and toward complying with these new programmatic hurdles. If this sudden change is, as Lilly claims, “part of [its] commitment to ensuring that the reduced prices offered through the 340B program help vulnerable patients,” Lilly should not impose needless administrative costs that prevent hospitals from providing comprehensive healthcare services to their rural and underserved communities.

What’s more, the data Lilly requires covered entities to submit to receive the statutory discount is not “readily available.” While some hospitals provide a limited amount of 340B contract pharmacy claims data to 340B ESP (the third-party web platform unilaterally chosen by Lilly), many hospitals do not. Moreover, before Lilly imposed its new requirements, no hospital provided medical claims data to 340B ESP (or any drug company). In addition, hospitals that currently submit data have experienced serious problems with the 340B ESP platform, and there

³ Medical claims data covers drugs administered in hospital outpatient or clinic settings, whereas pharmacy claims data concerns drugs dispensed through hospital-owned or -operated pharmacies.

are serious bugs and breakdowns in the technology. Lilly also makes no assurances that claims data will be protected and secure; hospitals and patients have legitimate patient and data privacy concerns.

Even though hospitals provide some data to payers, there are important differences between how that data is submitted for those purposes compared to what would be involved to submit data to Lilly. Claims data are submitted to payers through automated systems that have been built, tested and refined over a number of years. In contrast, these data policies would require hospitals to manually compile data that are housed in multiple disparate systems, provide it to their 340B third-party administrators, and then submit in the format that each drug company requires. Therefore, these data policies introduce a range of expensive, time-consuming and unnecessary burdens that hospitals do not face when submitting data to payers.

The best sign of how onerous Lilly's new policy will be on covered entities is how onerous its old one has been. Setting up the data feeds that are required to comply with Lilly's requirements involves hospitals weeks, if not months, of work in coordination with their 340B third-party administrator (TPA). But that is only the beginning. Lilly now demands several additional categories of claims data. The labor and vendor expenses required to comply with these expanded demands will exceed anything 340B hospitals have faced to date—and the burdens imposed to date already have been unnecessarily costly. To take just one example, unlike the data used to comply with Lilly's contract-pharmacy restrictions, data for in-house medical claims are often spread across multiple recordkeeping systems. Reconciling and aligning those systems would add significant complexity and cost to covered entities.

340B hospitals do not currently provide medical claims data to 340B ESP or any other vendor. Providing this data with the specific claim elements required by Lilly would be especially

burdensome, if not impossible. Unlike with pharmacy claims where the data is readily available, 340B TPAs do not have the information necessary to submit medical claims to 340B ESP, as that would require direct interface with a hospital's electronic medical record. Without those data connections, which not only take time and resources to establish but also carry serious data security and privacy risks, hospitals would need to *manually* provide that information to their TPA. This, too, would require hospitals to divert significant staff time and resources to ensure compliance with Lilly's new policy.

Lilly's announcement further states that the "340B ESP platform is the only way a covered entity can submit [claims-level data] under Lilly's policy." But even a limited initial rollout of 340B ESP revealed that the platform is rife with problems. Pricing is often loaded incorrectly, and claims are often wrongly denied for unknown reasons. As a result, hospitals have needed to devote significant staff time to resolving such problems, ensuring that accurate 340B pricing is provided, and challenging false denials. If problems have already occurred with a limited number of users, the bugs and blunders are certain to increase as more and more covered entities are required to use it. Those added mistakes, in turn, will increase costs for 340B covered entities because they must carefully monitor and fix inaccurate processing by 340B ESP.

Lilly is also incorrect in citing HRSA's announcement regarding the revised Rebate Program to support its assertions that "HRSA expressly endorsed requiring claims data" and that HRSA concluded that such requirements impose "minimal burden on covered entities." Lilly Opp'n 10–11. The Rebate Program is entirely distinct from Lilly's policy and only involves a small number of drugs. To our knowledge, HRSA has never stated that the new requirements imposed by Lilly's policy are not burdensome.

In fact, the cited passage of HRSA’s Revised 340B Rebate Model Pilot Program undermines—rather than supports—the reasonableness of Lilly’s claims data policy. The circumscribed data collection required under the Revised Rebate Pilot Program confirms HRSA’s well-founded concerns regarding burdens on covered entities forced to comply with onerous data collection policies. Upon considering the proper scope of claims data required for the Pilot Program, “HRSA intends to limit data collection manufacturers may impose on covered entities under the Pilot to the minimum necessary to effectuate rebate payments and support 340B program integrity and nonduplication under the MDPNP.” Notice Regarding 340B Rebate Model Pilot Program, 91 Fed. Reg. 48,883, 48,896 (Aug. 3, 2026) (emphasis added). Accordingly, HRSA explicitly rejected “broader reporting models” and “declined at this juncture to require additional data elements proposed by manufacturers, including purchasing data, encounter data, invoice-level information, and patient-level clinical information, because HRSA determined that collecting and reconciling such information could create additional operational complexity and systems burden for covered entities acclimating to a new rebate environment.” *Id.* at 48,896.

In any event, as AHA has explained to HRSA,⁴ the administrative costs of providing the claims data demanded by the proposed Rebate Program would divert *at least* half a billion dollars away from providing “more comprehensive services” and care for “more eligible patients.” H.R. Rep. No. 102-384, pt. 2, at 12 (1992). To make matters worse, HRSA’s estimates drastically understate the Rebate Program’s administrative costs. Hospitals have made clear that they will need to devote far more than two to five hours per week to comply with a rebate mechanism, which was HRSA’s estimate. AHA’s most conservative estimates are that a Rebate Program will require

⁴ Ltr. from AHA to Hon. Thomas J. Engels, Admin. of HRSA, Re: Request for Information: 340B Rebate Model Pilot Program (HRSA–2026–03042) (Apr. 20, 2026), <https://www.aha.org/system/files/media/file/2026/04/aha-response-to-hrsa-request-for-information-re-a-potential-340b-rebate-model-pilot-program-letter-4-20-2026.pdf>.

340B hospitals, on average, to hire at least one new full-time employee (FTE). Using HRSA’s own methodology, that estimate translates into a \$750 million price tag—just for 340B hospitals, just for one FTE, just for labor costs.

But that is not all. When the most conservative estimates of the Rebate Program’s other operational costs (*e.g.*, third-party vendors and TPAs, auditors, IT specialists, etc.) are added to that already-conservative labor cost estimate, the total administrative costs to 340B hospitals alone will exceed \$1 billion. “[T]hat’s billion with a b.” *White Stallion Energy Cir., LLC v. EPA*, 748 F.3d 1222, 1259 (D.C. Cir. 2014) (Kavanaugh, J., concurring in part and dissenting in part), *rev’d sub nom. Michigan v. EPA*, 576 U.S. 743 (2015).

Even more troubling, the suspension of 340B pricing will have immediate and far-reaching consequences for safety-net providers and the patients they serve. Many covered entities rely on 340B savings to support uncompensated care, rural health services, oncology programs, behavioral health treatment, pharmacy services, and other essential programs that would otherwise be difficult to sustain. Disruption to their access to 340B pricing threatens the financial stability of these providers and undermines access to care for underserved communities.

340B savings are especially important for another reason: the fragile state of 340B hospital finances. In stark contrast to the pharmaceutical industry, 340B hospitals typically operate with razor-thin (and often negative) margins.⁵ This is not surprising: 340B hospitals provide a disproportionate amount of uncompensated care to the country’s most vulnerable patients.⁶

⁵ AHA, *340B Drug Pricing Program: Fact vs. Fiction 3* (Apr. 2023), <https://www.aha.org/system/files/2018-04/340BFactvsFiction.pdf>; Allen Dobson *et al.*, *The Role of 340B Hospitals in Serving Medicaid and Low-income Medicare Patients* 12–13 (July 10, 2020), https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf.

⁶ See L&M Policy Research, LLC, *Analysis of 340B Disproportionate Share Hospital Services to Low-Income Patients* 1 (Mar. 12, 2018); AHA, *supra* note 15, at 3; Dobson, *supra* note 15, at 13–17.

Savings from the 340B program help to offset the cost of providing uncompensated health care. Contrary to Lilly's baseless suggestion that access to 340B drugs does not benefit patients, Lilly Opp'n 9, the Supreme Court has recognized that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *AHA v. Becerra*, 596 U.S. 724, 738 (2022).

CONCLUSION

For the foregoing reasons, *Amici* request that the Court grant MHMH's motion for preliminary injunction.

Dated: October 1, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Brief of *Amici Curiae* American Hospital Association, 340B Health, and New Hampshire Hospital Association in Support of Plaintiff's Motion for Preliminary Injunction was filed electronically on this 1st day of October 2026, and will, therefore, be served electronically upon counsel for the parties.

/s/ Michael A. Delaney

Michael A. Delaney, NH Bar No. 10504

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE**

MARY HITCHCOCK MEMORIAL HOSPITAL,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 1:26-cv-00616-SM-TSM

PROPOSED ORDER

AND NOW, on this ____ day of October 2026, after consideration of proposed *Amici Curiae* the American Hospital Association, 340B Health, and New Hampshire Hospital Association's Motion for Leave to File Brief as *Amici Curiae* Supporting Plaintiff's Motion for a Preliminary Injunction, and any response thereto, the Motion is hereby GRANTED.

The proposed brief filed as Exhibit A to the Motion shall be deemed filed and entered on the docket as a separate docket entry by the Clerk.

The Honorable Steven J. McAuliffe
United States District Court Judge

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE**

MARY HITCHCOCK MEMORIAL HOSPITAL,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Case No. 1:26-cv-00616-SM-TSM

**MEMORANDUM IN SUPPORT OF AMERICAN HOSPITAL ASSOCIATION, 340B
HEALTH, AND NEW HAMPSHIRE HOSPITAL ASSOCIATION’S MOTION FOR
LEAVE TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF’S MOTION
FOR PRELIMINARY INJUNCTION**

Under Local Rule 7.1(a)(2), proposed *Amici Curiae* the American Hospital Association, 340B Health, and the New Hampshire Hospital Association submit this memorandum in support of their motion for leave to file an *amicus* brief supporting Plaintiff’s motion for a preliminary injunction.

In this case, Plaintiff seeks to prevent Defendant from imposing onerous claims data policy in violation of state laws meant to protect consumers from unfair trade practices. The American Hospital Association (AHA), 340B Health, and New Hampshire Hospital Association (NHHA) (collectively, *Amici*) have a strong interest in the success of Plaintiff’s claims to protect hospitals from Defendant’s abusive conduct and can provide unique information and perspective to assist the Court in evaluating this matter. Thus, *Amici* seek leave to file their *amicus* brief in support of Plaintiff’s Motion for Preliminary Injunction.

ARGUMENT

District courts have broad discretion in deciding whether to accept *amicus* briefs. *League of Women Voters of New Hampshire v. Kramer*, No. 24-cv-73, 2024 WL 4604323, at *1 (D.N.H.

Oct. 29, 2024). “In weighing whether to grant amicus status, courts in this circuit have considered whether ‘there is an issue of general public interest, the amicus provides supplemental assistance to existing counsel, or the amicus insures a complete and plenary presentation of difficult issues so that the court may reach a proper decision.’” *United States v. Maine*, No. 1:24-cv-315-SDN, 2025 WL 2582122, at *2 (D. Me. Sept. 5, 2025) (internal citation omitted). Because neither the Federal Rules of Civil Procedure nor this Court’s Local Rules address *amicus* briefs, *Amici* have looked to the Federal Rule of Appellate Procedure 29 for guidance concerning the standards for filing an *amicus* brief. Because *Amici* meet the requirements of Fed. R. App. P. 29 and would assist the Court in resolving the issues before it on an issue of great public interest, we urge the Court to grant this motion.

Amici have unique information and perspective that can assist the Court in considering this matter. *Amici* include three hospital associations with members in New Hampshire that are committed to improving the health of the communities they serve through the delivery of high-quality, efficient, and accessible health care. *Amici* and their members benefit from the statutory discounts to which they are entitled under the federal 340B statute and would be greatly harmed if Defendant were permitted to violate state unfair trade practices laws through the imposition of its onerous claims data policy. Thus, *Amici* can provide the Court with a unique perspective and specific information about the impact of Defendant’s claims data policy that the parties cannot otherwise provide about hospitals in New Hampshire.

Granting leave will not delay proceedings or prejudice any party. *Amici* submitted its proposed brief on the deadline for Plaintiff’s submission of its Reply in support of its Motion for Preliminary Injunction without affecting the existing briefing schedule. Accordingly, *Amici* respectfully request the Court to grant their motion to file an *amicus* brief.

Dated: October 1, 2026

Respectfully submitted,

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I HEREBY CERTIFY that a true and correct copy of the foregoing Memorandum in Support of American Hospital Association, 340B Health, and New Hampshire Hospital Association's Motion for Leave to File Brief as *Amici Curiae* in Support of Plaintiff's Motion for Preliminary Injunction was filed electronically on this 1st day of October 2026, and will, therefore, be served electronically upon counsel for the parties.

/s/ Michael A. Delaney

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