

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

AMERICAN MEDICAL ASSOCIATION,
AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Civ. Action No. 1:21-cv-03231

**PLAINTIFFS' MOTION FOR STAY PENDING JUDICIAL REVIEW, OR IN THE
ALTERNATIVE, FOR SUMMARY JUDGMENT**

Pursuant to 5 U.S.C. § 705, Plaintiffs American Medical Association, American Hospital Association, Renown Health, UMass Memorial Health Care, Inc., Stuart M. Squires, M.D., and Victor F. Kubit, M.D., hereby move for a stay pending judicial review of specific and limited portions of an interim final rule titled “Requirements Related to Surprise Billing; Part II,” 86 Fed. Reg. 55,980 (Oct. 7, 2021). In the alternative, pursuant to Federal Rule of Civil Procedure 56, Plaintiffs move for summary judgment in their favor, provided Defendants consent to summary judgment proceedings on a mutually acceptable expedited schedule.¹

Plaintiffs seek relief by March 1, 2022—the approximate date arbitrations under the rule are scheduled to begin—in order to prevent irreparable harm to Plaintiffs Renown Health, UMass Memorial Health, Drs. Squires and Kubit, as well as the other members of Plaintiffs American Medical Association and American Hospital Association. In support of this motion, Plaintiffs submit the accompanying Memorandum of Points and Authorities and the Declarations of Bethany Sexton, Exhibit A (“Sexton Decl.”), Catherine M. Rossi, Exhibit B (“Rossi Decl.”), and Stuart M. Squires, M.D., Exhibit C (“Squires Decl.”). A proposed order is attached.

In accordance with LCvR 7.1(m), undersigned counsel have conferred with counsel for Defendants. To date, the parties have been unable to resolve the underlying dispute that forms the basis for this motion, and Defendants oppose this motion.

¹ Because this case involves “purely legal questions,” and there are no material facts or record evidence in dispute, *United States v. Philip Morris USA, Inc.*, 327 F. Supp. 2d 13, 17 (D.D.C. 2004), summary judgment is appropriate, provided Defendants consent to summary judgment proceedings on a mutually acceptable expedited schedule, *see Morris v. District of Columbia*, 38 F. Supp. 3d 57, 62 & n.1 (D.D.C. 2014) (converting a motion for preliminary injunction to a motion for summary judgment with the consent of the parties and citing *Curtis 1000, Inc. v. Suess*, 24 F.3d 941, 945 (7th Cir. 1994) (“The general point is that when the eventual outcome on the merits is plain at the preliminary injunction stage, the judge should, after due notice to the parties, merge the stages and enter a final judgment.”)).

Further, under LCvR 65.1(d), Plaintiffs are entitled to a hearing on this motion within 21 days of its filing. Due to the holidays, however, Plaintiffs would be amenable to a hearing during the first week of January or at another date convenient to the Court that will allow it to render a decision on this motion before March 1, 2022.

Respectfully submitted,

Dated: December 9, 2021

/s James E. Tysse

James E. Tysse
D.C. Bar No. 978722
Kelly M. Cleary
D.C. Bar No. 985642
Caroline L. Wolverton
D.C. Bar No. 496433
Daniel David Graver
D.C. Bar No. 1020026
Kristen E. Loveland (*admission pending*)
D.C. Bar No. 1684978
Akin Gump Strauss Hauer & Feld LLP
2001 K Street, N.W.
Washington, D.C. 20006
Telephone: (202) 887-4000
jtysse@akingump.com

*Counsel to Plaintiffs American Medical Association,
Stuart S. Squires, M.D., and Victor F. Kubit, M.D.*

Chad Golder
D.C. Bar No. 976914
Law Office of Chad Golder
514 6th Street, NE
Washington, DC 20002
Telephone: (203) 506-0670
golderlawoffice@gmail.com

*Counsel to Plaintiffs American Hospital Association,
Renown Health, and UMass Memorial Health Care,
Inc.*

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN MEDICAL ASSOCIATION,
AMERICAN HOSPITAL ASSOCIATION, *et al.*,

Plaintiffs,

v.

U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES, *et al.*,

Defendants.

Civ. Action No. 1:21-cv-03231

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR STAY
PENDING JUDICIAL REVIEW, OR IN THE ALTERNATIVE, FOR SUMMARY
JUDGMENT**

TABLE OF CONTENTS

INTRODUCTION1

BACKGROUND5

 I. Congress Enacts A Bipartisan, Bicameral Compromise To Address
 Surprise Medical Billing5

 II. The Departments Publish The September Rule As An Interim Final Rule .8

 III. The AMA, AHA, And Plaintiff Providers11

ARGUMENT14

 I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS15

 A. The Departments Acted Contrary To Law And In Excess Of Their
 Statutory Authority By Mandating A Presumption In Favor Of The
 QPA.....16

 B. The Departments’ Interpretation Of The Act’s Payment
 Determination Provision Is Owed No Deference.28

 II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM ABSENT A
 STAY33

 III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST
 STRONGLY FAVOR A STAY PENDING JUDICIAL REVIEW40

CONCLUSION.....42

STATUTORY AND REGULATORY ADDENDUM.....43

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Aamer v. Obama</i> , 742 F.3d 1023 (D.C. Cir. 2014)	15
<i>Aid Ass’n for Lutherans v. U.S. Postal Service</i> , 321 F.3d 1166 (D.C. Cir. 2003)	29
<i>Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.</i> , No. 20-CV-3377 (DLF), 2021 WL 1946376 (D.D.C. May 14, 2021).....	14
<i>Almendarez-Torres v. United States</i> , 523 U.S. 224 (1998).....	17
<i>*American Corn Growers Ass’n v. EPA</i> , 291 F.3d 1 (D.C. Cir. 2002)	19, 20, 21
<i>American Fuel & Petrochemical Mfrs. v. EPA</i> , 3 F.4th 373 (D.C. Cir. 2021).....	16, 28
<i>American Petroleum Inst. v. EPA</i> , 52 F.3d 1113 (D.C. Cir. 1995)	29
<i>Archdiocese of Wash. v. Washington Metro. Area Transit Auth.</i> , 897 F.3d 314 (D.C. Cir. 2018)	14
<i>Atlantic City Elec. Co. v. FERC</i> , 295 F.3d 1 (D.C. Cir. 2002)	15
<i>Bauer v. DeVos</i> , 325 F. Supp. 3d 74 (D.D.C. 2018)	14
<i>California v. Azar</i> , 911 F.3d 558 (9th Cir. 2018)	41
<i>Carlson v. Postal Regul. Comm’n</i> , 938 F.3d 337 (D.C. Cir. 2019)	19
<i>Central United Life Ins. Co. v. Burwell</i> , 827 F.3d 70 (D.C. Cir. 2016)	27
<i>Chaplaincy of Full Gospel Churches v. England</i> , 454 F.3d 290 (D.C. Cir. 2006)	34

**Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*,
467 U.S. 837 (1984)..... *passim*

Cigar Ass’n of Am. v. FDA,
317 F. Supp. 3d 555 (D.D.C. 2018).....14

Collins v. Yellen,
141 S. Ct. 1761 (2021).....20

Cuomo v. U.S. Nuclear Regulatory Comm’n,
772 F.2d 972 (D.C. Cir. 1985).....14

Curtis 1000, Inc. v. Suess,
24 F.3d 941 (7th Cir. 1994)2, 15

District of Columbia v. USDA,
444 F. Supp. 3d 1 (D.D.C. 2020).....38

Electronic Priv. Info. Ctr. v. FTC,
844 F. Supp. 2d 98 (D.D.C. 2012), *aff’d*, No. 12-5054, 2012 WL 1155661
(D.C. Cir. Mar. 5, 2012).....15

**Encino Motorcars, LLC v. Navarro*,
579 U.S. 211 (2016).....31, 32

Everglades Harvesting & Hauling, Inc. v. Scalia,
427 F. Supp. 3d 101 (D.D.C. 2019).....34, 39

Feinerman v. Bernardi,
558 F. Supp. 2d 36 (D.D.C. 2008).....33

Food & Water Watch, Inc. v. Vilsack
808 F.3d 905 (D.C. Cir. 2020).....39

Genus Med. Techs. LLC v. FDA,
994 F.3d 631 (D.C. Cir. 2021).....21

Pursuing Am.’s Greatness v. FEC,
831 F.3d 500 (D.C. Cir. 2016).....40

Grossmont Hosp. Corp. v. Burwell,
797 F.3d 1079 (D.C. Cir. 2015).....15

Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives,
920 F.3d 1 (D.C. Cir. 2019).....29

Gutierrez–Brizuela v. Lynch,
834 F.3d 1142 (10th Cir. 2016)28

King v. Burwell,
576 U.S. 473 (2015).....25

League of Women Voters v. Newby,
838 F.3d 1 (D.C. Cir. 2016).....38, 40

Levine v. Apker,
455 F.3d 71 (2d Cir. 2006).....17

Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach,
523 U.S. 26 (1998).....16

Michigan v. EPA,
576 U.S. 743 (2015).....24, 28, 29

Minney v. U.S. Office of Personnel Mgmt.,
130 F. Supp. 3d 225 (D.D.C. 2015).....36

Mylan Labs., Inc. v. Thompson,
332 F. Supp. 2d 106 (D.D.C. 2004).....15

New Hampshire Hosp. Ass’n v. Azar,
887 F.3d 62 (1st Cir. 2018).....31

NAACP v. Trump,
321 F. Supp. 3d 143 (D.D.C. 2018).....14

National Ass’n of Farmworkers Orgs. v. Marshall,
628 F.2d 604 (D.C. Cir. 1980).....32

National Tour Brokers Ass’n v. United States,
591 F.2d 896 (D.C. Cir. 1978).....31

New York v. DHS,
969 F.3d 42 (2d Cir. 2020).....41

Nken v. Holder,
556 U.S. 418 (2009).....40

Olu-Cole v. Haynes Pub. Charter Sch.,
930 F.3d 519 (D.C. Cir. 2019).....35

Padilla v. Rumsfeld,
352 F.3d 695 (2d Cir. 2003).....25

Palmer v. Massachusetts,
308 U.S. 79 (1939).....25

Pereira v. Sessions,
138 S. Ct. 2105 (2018).....28

Planned Parenthood Fed’n of Am., Inc. v. Heckler,
712 F.2d 650 (D.C. Cir. 1983).....21

**Public Service Co. of Indiana, Inc. v. ICC*,
749 F.2d 753 (D.C. Cir. 1984).....2, 19, 40

R.I.L-R v. Johnson,
80 F. Supp. 3d 164 (D.D.C. 2015).....40

RadLAX Gateway Hotel, LLC v. Amalgamated Bank,
566 U.S. 639 (2012).....30

Railway Labor Executives’ Ass’n v. National Mediation Bd.,
29 F.3d 655 (D.C. Cir. 1994).....29

Russello v. United States,
464 U.S. 16 (1983).....30

Sherley v. Sebelius,
644 F.3d 388 (D.C. Cir. 2011).....14

Smoking Everywhere, Inc. v. FDA,
680 F. Supp. 2d 62 (D.D.C. 2010).....33

SoundExchange, Inc. v. Copyright Royalty Bd.,
904 F.3d 41 (D.C. Cir. 2018).....29

Texas Children’s Hosp. v. Burwell,
76 F. Supp. 3d 224 (D.D.C. 2014).....38, 39

Texas v. EPA,
829 F.3d 405 (5th Cir. 2016)21

Trowell v. Beeler,
135 F. App’x 590 (4th Cir. 2005)19

**United Parcel Serv., Inc. v. Postal Regul. Comm’n*,
955 F.3d 1038 (D.C. Cir. 2020).....15, 18, 26

United States v. Cain,
583 F.3d 408 (6th Cir. 2009)32

United States v. Mead Corp.,
533 U.S. 218 (2001).....31

United States v. Palomar-Santiago,
141 S. Ct. 1615 (2021).....16

Utility Air Regulatory Grp. v. EPA,
573 U.S. 302 (2014).....27, 33

Utility Solid Waste Activities Grp. v. EPA,
236 F.3d 749 (D.C. Cir. 2001)31

VirtualAgility Inc. v. Salesforce.com, Inc.,
759 F.3d 1307 (Fed. Cir. 2014).....26

Wedelstedt v. Wiley,
477 F.3d 1160 (10th Cir. 2007)16

**Whitman-Walker Clinic, Inc. v. United States Dep’t of Health & Human Servs.*,
485 F. Supp. 3d 1 (D.D.C. 2020) *passim*

Winter v. Natural Res. Def. Council, Inc.,
555 U.S. 7 (2008).....14

Wisconsin Gas Co. v. FERC,
758 F.2d 669 (D.C. Cir. 1985)34, 39

Statutes

5 U.S.C.
 § 553(b)(B).....31
 § 702.....33
 § 705.....14
 § 706(2)(A)15

15 U.S.C. § 1116.....20

42 U.S.C.
 §300gg-111(a)(1)(C)(ii)5
 § 300gg-111(a)(1)(C)(iv)(I)6
 §300gg-111(a)(2)(B).....8
 § 300gg-111(a)(3)(E)(i)8
 § 300gg-111(a)(3)(K).....6
 § 300gg-111(b)(1)(A)5
 § 300gg-111(c)(1)(A).....6
 § 300gg-111(c)(2)30, 32
 § 300gg-111(c)(2)(A).....10
 § 300gg-111(c)(4)(A).....8, 21, 30
 § 300gg-111(c)(5)(A).....6, 16, 30
 § 300gg-111(c)(5)(A)(i).....6
 § 300gg-111(c)(5)(B)(i)(I)6

§ 300gg-111(c)(5)(C)..... *passim*
 § 300gg-111(c)(5)(C)(i).....7, 25, 26
 § 300gg-111(c)(5)(C)(ii).....7, 9, 18, 27
 § 300gg-111(c)(5)(E)(i)(II).....33

Other Authorities

45 C.F.R.
 § 149.140(b)(2)(iv)10
 § 149.510(a)(2)(v).....9, 18
 § 149.510(a)(2)(viii)9
 § 149.510(b)(4)(i)(A).....9
 § 149.510(b)(4)(ii)(A).....9, 17
 § 149.510(c)(4)(vi).....9

166 Cong. Rec. H7290 (Dec. 21, 2020).....22

Ban Surprise Billing Act, H.R. 5800, 116th Cong. § 2(a) (2020)23

Fed. R. Civ. P. 56(a)15

Sara Hansard, *Labor Official Defends Embattled Surprise Billing Rule*,
 Bloomberg Law (Nov. 10, 2021)10

Health and Human Services Department Fiscal Year 2022 Budget Request before
 the House Appropriations Sub-Committee (Apr. 15, 2021).....31

Letter from AHA to Chairman Neal on Surprise Medical Billing (Dec. 13, 2020)12

Letter from AMA to Chairman Neal and Ranking Member Brady on Surprise
 Medical Billing (Feb. 7, 2019).....11

Letter from Chairman Neal and Ranking Member Brady of the House Ways and
 Means Committee to Department Secretaries (Oct. 4, 2021)2, 8, 22, 23

Letter from Mark Werner, Blue Cross Blue Shield of North Carolina, to Provider
 (Nov. 5, 2021).....3, 34, 35

Letter from Members of Congress to Departments Secretaries (Nov. 5, 2021)23

Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019)23

Michael McAuliff, *Doctors Are Mad About Surprise Billing Rules. Becerra Says
 Stop Gouging Patients*, NPR (Nov. 22, 2021)2, 10, 11

Matt Mullarkey, *For the Love of the Game: A Historical Analysis and Defense of
 Final Offer Arbitration in Major League Baseball*, 9 Va. Sports & Ent. L.J.
 234 (2010).....6

No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019).....23

Press Release, House Ways & Means Comm., *Congressional Committee Leaders Announce Surprise Billing Agreement* (Dec. 11, 2020).....5, 22

Press Release, *Senator Murray Announces Bipartisan Deal to Protect Patients, End Surprise Medical Bills* (Dec. 11, 2020).....22

“Requirements Related to Surprise Billing; Part I,” 86 Fed. Reg. 36,872 (July 13, 2021)10

“Requirements Related to Surprise Billing; Part II,” 86 Fed. Reg. 55,980 (Oct. 7, 2021) *passim*

INTRODUCTION

Congress passed the No Surprises Act, Pub. L. 116-260, to protect patients from surprise medical bills and remove them from the middle of payment disputes between commercial health insurers (“insurers”) and medical care providers (“providers”). The No Surprises Act (the “Act”) accomplishes this by establishing an independent dispute resolution (“IDR”) process in which an independent arbitrator settles payment disputes between insurers and providers based on its review of six mandatory statutory factors that the arbitrator “shall” consider. 42 U.S.C. § 300gg-111(c)(5)(C). The IDR process in general, and the enumerated factors in particular, reflect Congress’s intentionally balanced approach to ensuring fair payment for healthcare services. For years, Plaintiffs American Medical Association (“AMA”) and American Hospital Association (“AHA”)—the nation’s leading member associations of physicians and hospitals, respectively—strongly supported protecting patients from “surprise billing,” and they welcomed Congress’s solution.

In direct conflict with the Act’s text and design, Defendants the United States Department of Health and Human Services (“HHS”), Department of Labor, Department of the Treasury, and Office of Personnel Management (collectively, the “Departments”) issued an interim final rule (the “September Rule”) that barely resembles the IDR process that Congress created. *See* “Requirements Related to Surprise Billing; Part II,” 86 Fed. Reg. 55,980 (Oct. 7, 2021). Instead of Congress’s balanced approach, the September Rule places a heavy thumb on the scale in favor of just one of the factors that Congress directed the independent arbitrator to consider. Specifically, the September Rule requires arbitrators to “presume” that one factor—the Qualifying Payment Amount (“QPA”)—reflects the appropriate payment rate. The Departments are wrong to call this the “best interpretation” of the statute. 86 Fed. Reg. at 55,996. In fact, the September Rule directly conflicts with the Act because “Congress carefully avoided attaching any particular

weights to the various factors that must be taken into account,” *Public Service Co. of Indiana, Inc. v. ICC*, 749 F.2d 753, 763 (D.C. Cir. 1984), and it surely did not assign any one statutory factor presumptive weight. Every tool of statutory construction—from text to structure to purpose to legislative history—demonstrates just how far the Departments have overreached.

Congress gave the independent arbitrator discretion to weigh the statutorily mandated factors in order to reach a fair resolution of each payment dispute. As the Act’s principal architects recently explained, “Congress deliberately crafted the law to avoid any one factor tipping the scales during the IDR process”—yet the September Rule “strays from the No Surprises Act in favor of an approach that Congress did not enact in the final law.” Letter from Chairman Neal and Ranking Member Brady of the House Ways and Means Committee to Department Secretaries, (Oct. 4, 2021) (“Neal and Brady Letter”), <https://www.gnyha.org/wp-content/uploads/2021/10/2021.10.04-REN-KB-Surprise-Billing-Letter80.pdf>. The Departments’ reading of the No Surprises Act distorts this bicameral, bipartisan compromise and undermines the Act’s purpose of protecting patients.

Plaintiffs Renown Health, UMass Memorial Health Care, Inc. (“UMass Memorial Health”), Stuart M. Squires, M.D., Victor F. Kubit, M.D., the other provider members of the AMA and AHA, and the patients that they all care for will suffer severe and irreparable harm as a result of the September’s Rule illegal presumption. Most directly, out-of-network healthcare providers will suffer irreparable harm because the September Rule’s presumption in favor of the QPA will prevent fair and adequate compensation for their healthcare services, and they cannot recover underpayments through damages suits. HHS Secretary Xavier Becerra recently admitted as much, telling healthcare providers that they would “have to tighten their belt[s]” under the Departments’ new rules. Michael McAuliff, *Doctors Are Mad About Surprise Billing Rules. Becerra Says Stop*

Gouging Patients, NPR (Nov. 22, 2021) (“NPR Becerra Interview”), <https://www.npr.org/sections/health-shots/2021/11/22/1057985191/becerra-defends-hhs-rules-aimed-at-reining-in-surprise-medical-bills>. In-network providers will face a similar threat, as insurers demand cuts in payment rates to match the rates they expect to receive through the IDR process—and threaten cancellation of contracts if the providers do not agree. In fact, one insurer recently demanded that a provider accede to a “significant reduction in your contracted rate” based on the “clarity” provided in the September Rule. Letter from Mark Werner, Blue Cross Blue Shield of North Carolina, to Provider (Nov. 5, 2021) (“BCBS Letter”), <https://tinyurl.com/y3dfvtts>.

The attached declarations demonstrate that these injuries more than “clear the irreparable-harm threshold.” *Whitman-Walker Clinic, Inc. v. United States Dep’t of Health & Human Servs.*, 485 F. Supp. 3d 1, 57 (D.D.C. 2020). Plaintiffs Renown Health and UMass Memorial Health explain that the QPA-presumption will have “devastating” effects on their non-profit hospitals and the low-income and rural communities they serve. Sexton Decl. ¶ 26; Rossi Decl. ¶ 30. As it is, these hospitals offer a range of vital healthcare services that already operate at a loss. The September Rule will further starve those services of the resources needed to keep them going at the same levels. *See* Sexton Decl. ¶ 28 (identifying trauma, mental health services, Medicaid, indigent women and children’s care, and the children’s hospital pediatric subspecialties as those that would face potential reductions); Rossi Decl. ¶ 30 (identifying community-based mobile medical services for indigent families and youth, food insecurity assistance care, and pediatric asthma intervention for low-income youth as services that would face potential reductions). The unlawful September Rule will thus stand in the way of these hospitals’ missions of improving the health of all members of their communities, including poor and underserved patients. *See* Sexton

Decl. ¶ 27; Rossi Decl. ¶ 29. Plaintiff Dr. Squires further explains that the QPA presumption will consistently undercompensate his and co-Plaintiff Dr. Kubit's anesthesiology practice in rural North Carolina when it provides out-of-network medical services. Squires Decl. ¶ 10. He also anticipates an in-network insurer, Blue Cross Blue Shield of North Carolina, will use the QPA-presumption as leverage to demand in-network payment rates far below the value of the practice's services. *Id.* at ¶¶ 12-13, 18-19. If consistently undercompensated, Drs. Squires' and Kubit's practice may be forced to reduce its hours and terminate contracts with local hospitals. *Id.* at ¶ 21. As a small practice, it may ultimately be forced to close, depriving the patients in their rural area of much-needed medical services. *Id.* at ¶ 22.

Most troublingly, patients will suffer from the September Rule. With fewer insurance and provider choices, the Rule will seriously reduce patients' access to healthcare. Rather than deny these effects, the Departments explicitly admitted during rulemaking that "undercompensation could threaten the viability of these providers [and] facilities," which, "in turn, could lead to participants, beneficiaries and enrollees not receiving needed medical care." 86 Fed. Reg. at 56,044. Yet the Departments issued the September Rule anyway. Congress enacted the No Surprises Act to protect patients—not to harm them in this manner.

Because these aspects of the September Rule are manifestly contrary to law and will irreparably harm Plaintiffs and their members, this Court should stay those provisions of the September Rule requiring arbitrators to employ a presumption in favor of the QPA, or, in the alternative, grant summary judgment in Plaintiffs' favor.

BACKGROUND

I. Congress Enacts A Bipartisan, Bicameral Compromise To Address Surprise Medical Billing

On December 27, 2020, Congress enacted the No Surprises Act, “a bipartisan, bicameral deal . . . to protect patients from surprise medical bills and promote fairness in payment disputes between insurers and providers.” Press Release, House Ways & Means Comm., *Congressional Committee Leaders Announce Surprise Billing Agreement* (Dec. 11, 2020), <https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement>.² Prior to the No Surprises Act, when a patient received care from an out-of-network provider, the provider submitted a bill to the patient’s insurer, and the insurer determined how much to pay the provider. The outstanding balance—the difference between what the provider billed and what the insurer paid—was the patient’s responsibility. To collect that balance, providers traditionally sent patients “balance bills,” sometimes called “surprise bills” because patients often received them when they had no choice in their care, such as in the case of emergency care or care provided by an ancillary healthcare provider (such as an out-of-network clinical lab).

To protect patients from such “surprise bills,” the No Surprises Act restricts out-of-network providers’ ability to bill patients in excess of what the patient would have paid had she been treated by an in-network provider. 42 U.S.C. § 300gg-111(a)(1)(C)(ii), (b)(1)(A). The Act does not,

² The Act, which was passed as part of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 tit. I, div. BB, made parallel amendments to provisions of the Public Health Service (“PHS”) Act, which is enforced by the Department of Health and Human Services (“HHS”); the Employee Retirement Income Security Act (“ERISA”), which is enforced by the Department of Labor; and the Internal Revenue Code (“IRC”), which is enforced by the Department of the Treasury. These Departments, along with the Office of Personnel Management (“OPM”) (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the September Rule.

however, expect providers to absorb underpayments. The Act instead provides a process by which providers can seek fair and reasonable payment from insurers. Insurers will continue to send the provider an initial payment or notice of denial of payment, but if a provider believes it to be an underpayment, the provider may initiate a 30-day period of open negotiation with the insurer. *See Id.* § 300gg-111(a)(1)(C)(iv)(I), (a)(3)(K), (c)(1)(A). If the insurer and provider are unable to reach agreement during that 30-day period, either party may initiate binding arbitration before an independent dispute resolution (“IDR”) arbitrator, who determines the fair payment amount. *Id.* § 300gg-111(a)(3)(K), (c)(1)(B).

In IDR arbitration, each party must submit their best and final offer, and the independent arbitrator must select one of the offers. 42 U.S.C. § 300gg-111(c)(5)(A)(i), (c)(5)(B)(i)(I). The Act thus establishes a “baseball-style” process designed to encourage the parties to reach a pre-arbitration compromise or, failing that, to make only reasonable, well-supported offers. *See Matt Mullarkey, For the Love of the Game: A Historical Analysis and Defense of Final Offer Arbitration in Major League Baseball*, 9 Va. Sports & Ent. L.J. 234, 245 (2010) (explaining that baseball-style arbitration encourages reasonable offers because, if one party’s offer is unreasonable, the arbitrator will select the other party’s offer even if it is too high or low).

The Act explicitly sets forth several mandatory factors that the arbitrator “shall” consider in deciding which offer to select (the “Subparagraph C Factors”). 42 U.S.C. § 300gg-111(c)(5)(C) (“In determining which offer is the payment to be applied pursuant to this paragraph, the certified [arbitrator] . . . shall consider” six different factors.); *see id.* § 300gg-111(c)(5)(A) (“[T]he certified [arbitrator] shall[,] taking into account the considerations in subparagraph (C), select one of the offers[.]”). Specifically, in a section titled “Considerations in determination,” Congress instructs that, “[i]n determining which offer is the payment to be applied,” the arbitrator “shall consider”:

(I) the qualifying payment amounts [QPAs] . . . for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; *and*

(II) subject to subparagraph D, information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

42 U.S.C. § 300gg-111(c)(5)(C)(i) (emphasis added). As incorporated in subsection II above,

“clause (ii)” lists the following five factors that the arbitrator “shall” consider:

(I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).

(II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.

(III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.

(IV) The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.

(V) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

Id. § 300gg-111(c)(5)(C)(ii). The arbitrator also must consider any information she requests from the parties, *id.* § 300gg-111(c)(5)(C)(i)(II), as well as any additional information submitted by either party relating to its offer, *id.* § 300gg-111(c)(5)(C)(ii). Congress further specified three factors that the arbitrator “shall not consider”: (1) usual and customary charges, (2) the amount the provider would have billed for the item or service if the Act’s billing provisions did not apply, and (3) the amount a public payer (like Medicare) would have paid. *Id.* § 300gg-111(c)(5)(D). Finally, Congress required the independent arbitrator to have “sufficient medical, legal, and other

expertise” to be able to assess all the Subparagraph C Factors and come to a conclusion as to the best offer based on those factors. *Id.* § 300gg-111(c)(4)(A).

Calculated by the insurer, the QPA is generally the median of the contracted rates recognized by an insurer for the same or similar services in the same geographic region. 42 U.S.C. § 300gg-111(a)(3)(E)(i); *see also id.* § 300gg-111(a)(2)(B). Initially, Congress considered adopting proposals that would have made the QPA the presumptive benchmark in the arbitrator’s selection. *See* Neal and Brady Letter (“Multiple proposals that ultimately did not become law relied on the median in-network rate [effectively, the QPA] as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate.”). But Congress ultimately rejected this approach, prescribing no particular weight or presumption for any one factor. Instead, Congress mandated that the arbitrator “shall” consider *all* of the enumerated factors, leaving it to the independent arbitrator’s discretion and expertise to decide how much weight to give each factor in a particular case.

II. The Departments Publish The September Rule As An Interim Final Rule

More than nine months after Congress passed the No Surprises Act, the Departments published the September Rule, an interim final rule that became effective on October 7, 2021. *See* 86 Fed. Reg. 55,980. As relevant here, the Departments purported to implement provisions related to the arbitrator’s payment determination—even though the Act’s provision governing payment determinations does not delegate any substantive authority to the Departments. Specifically, the Departments imposed a novel “presumption” that one of the factors—the QPA—“is [the] appropriate” payment rate, and that (with rare exception) the arbitrator “*must* select the offer closest to the QPA[.]” 86 Fed. Reg. at 55,995 (emphasis added). Despite the Act’s language that IDR arbitrators “shall” consider all of the Subparagraph C Factors, under the September Rule, the arbitrator may consider the non-QPA factors only to the extent a party provides “credible

information” that “clearly demonstrates” that the QPA is “materially different” from the appropriate payment rate. 45 C.F.R. § 149.510(b)(4)(ii)(A); *see id.* § 149.510(a)(2)(v) (defining “credible information” as “information that upon *critical analysis* is worthy of belief and is trustworthy” (emphasis added)); *id.* § 149.510(a)(2)(viii) (defining “material difference” to mean “a *substantial* likelihood that [an IDR arbitrator] . . . would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate” (emphasis added)).

The September Rule discourages consideration of the non-QPA factors in additional ways. For instance, the September Rule does not require the parties to submit, or the arbitrator to obtain, information related to any other statutorily mandated factor at all. *See* 45 C.F.R. § 149.510(b)(4)(i)(A). Indeed, the Departments warn arbitrators that certain Subparagraph C Factors that Congress chose—such as the “level of training [and] experience” of the provider and the acuity of the patient or complexity of the service, 42 U.S.C. §§ 300gg-111(c)(5)(C)(ii)(I), (III)—should rarely trump the QPA, based on the Departments’ belief that specific statutory language must bow to the Act’s general “goals.” *See* 86 Fed. Reg. at 55,997. In addition, the September Rule places a special burden on arbitrators who deviate from the QPA. If the arbitrator does not select the offer closest to the QPA, she must provide a “detailed explanation” of why she found the QPA to be materially different from the appropriate rate, including a description of “the additional considerations relied upon, whether the information about those considerations submitted by the parties was credible, and the basis upon which the certified [arbitrator] determined that the credible information demonstrated that the QPA is materially different from the appropriate out-of-network rate.” 86 Fed. Reg. at 56,000; *see* 45 C.F.R. § 149.510(c)(4)(vi). The Rule contains no such requirement if the arbitrator selects the offer closest to the QPA.

The QPA will typically undervalue the services that physicians and hospitals provide, in large part due to the methods Defendants chose for calculating the QPA.³ This is why Secretary Becerra recently informed healthcare providers that they—and not insurers—would “have to tighten their belt[s]” under the Departments’ new rules. *See* NPR Becerra Interview. Indeed, the Departments have admitted that an intended effect of making the QPA the presumptive factor is to limit “higher out-of-network rates” paid to providers. *E.g.*, 86 Fed. Reg. at 55,996 (noting that the September Rule will limit “higher out-of-network rates”).

The Departments were given a year—until December 27, 2021—to stand up the IDR process. *See* 42 U.S.C. § 300gg-111(c)(2)(A). The Departments nonetheless decided to publish the Rule as an interim final rule at the end of September 2021, without first considering public notice and comment. The Departments claimed that “it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final rules in place until a full public notice and comment process has been completed[.]” 86 Fed. Reg. at 56,043.

Although the September Rule is already in effect, the Departments invited the public to submit any comments by December 6, 2021. The Departments, however, did not commit to a date by which they would issue a final rule, and multiple recent reports have suggested that the Departments are unlikely to change the September Rule following notice and comment. *E.g.*, Sara

³ Specifically, in an interim final rule issued in July 2021, the Departments concluded that the median contracted rate—on which the QPA is based—should be calculated by (1) using each contract, rather than the number of claims actually paid at a contracted rate, as a data point; (2) excluding single case agreements; (3) ignoring certain elements of contracted rates that would increase the median contracted rate, including risk-sharing, bonus, and incentive payments; and (4) defining the geographic region to include, in some instances, rates in other states. *See* 45 C.F.R. § 149.140(b)(2)(iv); “Requirements Related to Surprise Billing; Part I,” 86 Fed. Reg. 36,872, 36,889 (July 13, 2021). The end result is that providers will usually receive lower payments under a regime controlled by the QPA versus one in which no single Subparagraph C Factor takes precedence. The QPA will particularly undervalue medical services where insurers have historically underpaid providers or have not made good-faith efforts to enter network agreements.

Hansard, *Labor Official Defends Embattled Surprise Billing Rule*, Bloomberg Law (Nov. 10, 2021), <https://news.bloomberglaw.com/employee-benefits/labor-official-defends-embattled-surprise-billing-rule> (“‘Obviously we did take an approach in the interim final rule that wasn’t an accident. We’ve been thinking about this issue a lot, and it was a deliberate decision,’ Ali Khawar, assistant secretary of the DOL’s Employee Benefits Security Administration, said[.]”); NPR Becerra Interview (including similar quotes from Secretary Becerra and observing that “[r]ules that are this far along tend to go into effect with little or no changes”).

III. The AMA, AHA, And Plaintiff Providers

The American Medical Association is the largest professional association of physicians, residents, and medical students in the United States. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. The American Hospital Association represents nearly 5,000 hospitals, healthcare systems, and other healthcare organizations. Founded in 1898, the AHA educates its members on healthcare issues and advocates on their behalf so that their perspectives are heard and addressed in national health policy development, legislative and regulatory debates, and judicial matters. Both the AMA and AHA strongly support Congress’s goal of protecting patients from “surprise billing.” For years, the AMA and AHA consistently advocated for a solution to surprise billing that would shield patients from unexpected medical bills, while enabling providers and insurers to determine fair payment among themselves.⁴

Plaintiff Renown Health is an integrated healthcare system based in Reno, Nevada. It is northern Nevada’s largest locally governed, not-for-profit healthcare network. It includes four

⁴ See, e.g., Letter from AMA to Chairman Neal and Ranking Member Brady on Surprise Medical Billing (Feb. 7, 2019), <https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTER>

hospitals, 100 sites for primary, urgent, and specialty care; telehealth; and an integrated, provider-sponsored health insurance plan and accountable care organization that serves more than 150,000 members across northern Nevada. It provides the region's only Level II Trauma Center, serving over one million people and 100,000 square miles, from Sacramento to Salt Lake City. Renown also provides the region's first and only children's emergency room, which was opened in 2009. This broad reach allows Renown Health to provide desperately needed health and medical services to those living in remote, rural communities. Indeed, for rural Nevada and regions in Northeastern California, Renown is the safety-net provider for patients with chronic conditions and other serious health conditions. Given the vast health disparities that Nevada residents experience, including high mortality rates for chronic conditions such as heart disease, cancer, chronic respiratory disease, and mental health, Renown has set out to combat Nevada's history of ranking near the bottom of overall health rankings in the United States.

Plaintiff UMass Memorial Health is the largest healthcare system in Central and Western Massachusetts. It is a nonprofit network that makes healthcare accessible for all, regardless of ability to pay. In 1997, the creation of UMass Memorial Health was authorized by state legislation that approved combining the nonprofit Memorial Hospital with the public University of Massachusetts Medical Center. While allowing the combination of these entities into a new private, nonprofit system, the legislation also mandated that UMass Memorial Health permanently fulfill a unique, three-part public mission: (1) to provide highly specialized clinical services unavailable elsewhere in Central Massachusetts, (2) to provide free care to indigent patients, and

S%2F2019-2-7-Surprise-Billing-Ways-and-Means-Signon.pdf; Letter from AHA to Chairman Neal on Surprise Medical Billing (Dec. 13, 2020), https://www.aha.org/system/files/media/file/2020/12/AHA-Letter-No-Surprises-Act_12-13-20.pdf.

(3) to support the Commonwealth's only public medical school. Consistent with that mission, UMass Memorial Health serves some of the most vulnerable patients and communities in Massachusetts.

UMass Memorial Health includes four hospitals: UMass Memorial Medical Center (Worcester), UMass Memorial Health – HealthAlliance-Clinton Hospital (Fitchburg, Clinton and Leominster), UMass Memorial Health – Marlborough Hospital (Marlborough), and UMass Memorial Health – Harrington Hospital (Southbridge). UMass Memorial Health also includes the only designated Level I Trauma Center for adults in Central Massachusetts and the region's only Level III Neonatal Intensive Care Unit, which provides expert care for ill or premature newborns. In addition to its fully equipped medical centers, UMass Memorial Health also includes a home health and hospice program, and community-based physician practices. UMass Memorial Health also has invested in a range of health-related joint ventures in the Central Massachusetts region, including an affiliation with CareWell Urgent Care to provide regional urgent care services and a joint venture with Shields Health Care to establish the Surgery Center in Shrewsbury, Massachusetts where UMass Memorial Medical Group physicians and other local physicians provide high-quality, low-cost outpatient surgery services. UMass Memorial Health also includes Community Healthlink, the region's largest comprehensive provider of behavioral health, substance use disorder, and homelessness services.

Plaintiffs Stuart M. Squires, M.D., and Victor F. Kubit, M.D., are licensed physicians and practicing anesthesiologists who practice with Cumberland Anesthesia Associates in Fayetteville, NC. Dr. Squires also serves as the practice's president. Both Drs. Squires and Kubit are members in good standing of the AMA. Dr. Squires has practiced at Cumberland for over 21 years, and Dr. Kubit for 20 years. Cumberland provides anesthesia services at several local hospitals, including

Cape Fear Valley Medical Center in Fayetteville, NC; Betsy Johnson Hospital in Dunn, NC; and Central Harnett Hospital in Lillington, NC. Cumberland provides its services in connection with a full range of medical procedures, including a substantial amount of obstetrics services. Their practice treats all patients without regard to their insured status or ability to pay.

ARGUMENT

This Court should stay the specific and limited provisions of the September Rule that require IDR arbitrators to presumptively favor the QPA. *See* 5 U.S.C. § 705. Motions to stay agency action are reviewed under the same standard as requests for preliminary injunctive relief. *See Cuomo v. U.S. Nuclear Regulatory Comm’n*, 772 F.2d 972, 974 (D.C. Cir. 1985); *Bauer v. DeVos*, 325 F. Supp. 3d 74, 105 (D.D.C. 2018). The Court has discretion to grant a preliminary injunction if (1) Plaintiffs are “likely to succeed on the merits,” (2) Plaintiffs are “likely to suffer irreparable harm in the absence of preliminary relief,” (3) “the balance of equities tips in [Plaintiffs’] favor,” and (4) the provision of interim relief “is in the public interest.” *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011).

Courts in this Circuit continue to assess the preliminary injunction factors “on a sliding scale, whereby a strong showing on one factor could make up for a weaker showing on another.” *NAACP v. Trump*, 321 F. Supp. 3d 143, 146 (D.D.C. 2018) (internal quotation marks omitted) (quoting *Cigar Ass’n of Am. v. FDA*, 317 F. Supp. 3d 555, 560 (D.D.C. 2018)); *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, No. 20-CV-3377 (DLF), 2021 WL 1946376, at *1 (D.D.C. May 14, 2021) (under sliding scale approach, Plaintiff must show at least “a serious legal question on the merits”); *see Archdiocese of Wash. v. Washington Metro. Area Transit Auth.*, 897 F.3d 314, 334 (D.C. Cir. 2018) (reserving question of “whether the ‘sliding scale’ approach remains valid after” *Winter*). Whether a plaintiff has “established a likelihood of

success on the merits” nonetheless remains the “most important factor.” *Aamer v. Obama*, 742 F.3d 1023, 1038 (D.C. Cir. 2014); *see Electronic Priv. Info. Ctr. v. FTC*, 844 F. Supp. 2d 98, 101 (D.D.C. 2012) (“The likelihood of success requirement is the most important of [the preliminary injunction] factors.”), *aff’d*, No. 12-5054, 2012 WL 1155661 (D.C. Cir. Mar. 5, 2012). Because Plaintiffs have an overwhelming likelihood of success on the merits, they are entitled to a stay regardless of whether the sliding scale approach applies.

In the alternative, this Court should grant summary judgment under Federal Rule of Civil Procedure 56 for the reasons explained below. A court may grant a motion for summary judgment if “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). Because this case presents “purely legal issues,” *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 116 (D.D.C. 2004), and because those issues should be resolved in Plaintiffs’ favor, summary judgment is appropriate here, provided Defendants consent to summary judgment proceedings on a mutually acceptable expedited schedule. *See generally Curtis 1000, Inc. v. Suess*, 24 F.3d 941, 945 (7th Cir. 1994) (“The general point is that when the eventual outcome on the merits is plain at the preliminary injunction stage, the judge should, after due notice to the parties, merge the stages and enter a final judgment.”).

I. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A reviewing court must “set aside agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Grossmont Hosp. Corp. v. Burwell*, 797 F.3d 1079, 1085 (D.C. Cir. 2015) (internal quotation marks and citation omitted); *see* 5 U.S.C. § 706(2)(A). “An agency Order that is at odds with the requirements of the applicable statute cannot survive judicial review.” *United Parcel Serv., Inc. v. Postal Regul. Comm’n*, 955 F.3d 1038, 1050 (D.C. Cir. 2020); *see Atlantic City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (“In the absence of statutory authorization for its act, an agency’s action is plainly contrary to law and

cannot stand.” (internal quotation marks and citation omitted)). Considering the “traditional tools of statutory construction,” including “the provision’s text, context, legislative history, and purpose,” *American Fuel & Petrochemical Mfrs. v. EPA*, 3 F.4th 373, 380 (D.C. Cir. 2021), the September Rule is contrary to the unambiguous terms of the No Surprises Act.

A. The Departments Acted Contrary To Law And In Excess Of Their Statutory Authority By Mandating A Presumption In Favor Of The QPA

1. The September Rule Conflicts With The No Surprises Act’s Text And Design

The September Rule unlawfully conflicts with the No Surprises Act’s unambiguous text and design in numerous ways.

First, the September Rule conflicts with the Act’s direction that, in deciding which offer to select, the arbitrator shall consider all six statutory factors in every case. Congress twice instructed the arbitrator that she “shall” consider *all* the Subparagraph C Factors in determining which offer is the best. The Act first mandates that “the certified [arbitrator] *shall* . . . select one of the offers” after “taking into account the considerations specified in subparagraph (C).” 42 U.S.C. § 300gg-111(c)(5)(A) (emphasis added). The Act then reiterates that “[i]n determining which offer is the payment to be applied pursuant to this paragraph, the certified [arbitrator] . . . *shall* consider” the Subparagraph C Factors. *Id.* § 300gg-111(c)(5)(C) (emphasis added). Where, as here, a statute “comes in terms of the mandatory ‘shall,’” it “creates an obligation impervious to judicial”—or agency—“discretion.” *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 35 (1998). Similarly, “[t]he statute’s use of the word ‘and’ between the [factors] provides clear indication that *all* [six] factors are to be considered” by the arbitrator when determining the appropriate payment rate. *Wedelstedt v. Wiley*, 477 F.3d 1160, 1165-66 (10th Cir. 2007) (emphasis added); *see United States v. Palomar-Santiago*, 141 S. Ct. 1615, 1620-21 (2021) (“The requirements are connected by the conjunctive ‘and,’ meaning defendants must meet all

three.”); *Levine v. Apker*, 455 F.3d 71, 81 (2d Cir. 2006) (“Significantly, Congress used the word ‘and’ rather than ‘or’ to unify its five concerns. All of the listed factors must therefore be considered.”). What is more, the title of the relevant subsection is “Considerations in determination.” 42 U.S.C. § 300gg-111(c)(5)(C). Not only does this title say nothing about a favored or presumptive consideration, but its plain text instructs that all of the factors listed therein are “considerations” for the arbitrator’s payment determination. *See Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) (“[T]he title of a statute and the heading of a section are tools available for the resolution of a doubt about the meaning of a statute.” (internal quotation marks and citation omitted)).

In the September Rule, however, the Departments dictated that the arbitrator must ignore the non-QPA factors unless a party first meets a heightened standard—*i.e.*, the party must “clearly demonstrate[]” the QPA is “materially different” from the appropriate payment rate. 45 C.F.R. § 149.510(b)(4)(ii)(A). Indeed, the Rule makes clear that, despite Congress’s decision to require arbitrators to consider all six factors, the Departments believe that certain non-QPA factors should rarely “necessitate an out-of-network rate higher than the offer closest to the QPA.” 86 Fed. Reg. at 55,997. Relying on the example of “the simple repair of a superficial wound,” the Departments explain that they believe the training or experience of a provider should almost never necessitate a rate higher than the QPA. *Id.* But contrary to the Departments’ assertion, the “simple” repair of such wounds is often not so simple. Their position fails to take account of added complications, such as the fact that patients with “simple” wounds may often have extenuating circumstances such as substance use or psychiatric disorders that complicate a repair, or that homeless patients are less likely to have the ability to keep such a wound clean and uninfected, creating a host of related medical issues. A provider’s training and experience in managing those patients matters,

and managing them requires greater resources and time. In addition, patients often require emergency care for numerous reasons other than superficial wounds—such as for pulmonary embolisms, gunshot wounds, ectopic pregnancies, and strokes—where treatment by experienced providers matters as well. More fundamentally, the Departments have no authority to discard Congress’s judgment that training and experience are important considerations in determining the appropriate payment rate, even if they disagree with it. *Cf.* 42 U.S.C. § 300gg-111(c)(5)(C)(ii)(I) (arbitrator “shall” consider “[t]he level of training [and] experience . . . of the provider”).

Moreover, the Rule explicitly instructs the arbitrator to consider the evidence related to the non-QPA factors with skepticism. *See* 45 C.F.R. § 149.510(a)(2)(v) (defining “credible information” as “information that upon *critical analysis* is worthy of belief and is trustworthy” (emphasis added)). That is true even though the September Rule affirmatively *forbids* the arbitrator from scrutinizing the QPA, commanding her to take the insurer’s proffered QPA as given. *See* 86 Fed. Reg. at 55,996 (“[I]t is not the role of the certified IDR entity to determine whether the QPA has been calculated by the [insurer] correctly.”). As such, some statutory factors may be cast aside before they are even considered if they do not meet the Rule’s high “critical analysis” standard. The QPA, on the other hand, must always be considered, even if an arbitrator is dubious about its accuracy. To be clear: Plaintiffs have always assumed that parties would submit credible evidence and that arbitrators would take credibility into account when analyzing each of the statutorily mandated factors. Plaintiffs’ objection is that the September Rule sets up a skeptical, one-sided evidentiary burden that is found nowhere in the statute and makes it more difficult for the arbitrator to fairly consider all six statutory factors as Congress intended.

These features of the September Rule are contrary to law. “A statutorily mandated factor, by definition, is an important aspect of any issue” under consideration. *United Parcel Serv.*, 955

F.3d at 1050-51. An agency is therefore not “free to ignore any [such] factor entirely,” or to instruct another entity to do so. *Carlson v. Postal Regul. Comm’n*, 938 F.3d 337, 344 (D.C. Cir. 2019). Nor can an agency alter a statutorily imposed burden of proof, as the Departments do here. *See Public Service Co. of Indiana, Inc.*, 749 F.2d at 765-66. Accordingly, the September Rule violates Congress’s unambiguous command for the arbitrator to independently consider *all* of the statutory factors, in every case, in deciding which offer to select.

Second, the September Rule conflicts with the No Surprises Act by treating “the QPA [as] the presumptive factor” in selecting a payment offer. 86 Fed. Reg. at 55,996. By inventing a “presumption that the QPA is the appropriate payment amount”—a requirement found nowhere in the Act—the Departments have violated Congress’s decision to prescribe factors for the arbitrator’s consideration without giving any one factor controlling weight. Where, as here, Congress has “carefully avoided attaching any particular weights to the various concerns that must be taken into account,” an agency cannot “select . . . one [statutorily mandated] factor as controlling.” *Public Service Co. of Indiana, Inc.*, 749 F.2d at 763; *see id.* at 765 (“One statutory factor cannot be isolated out of context, or blindly exalted at the expense of others that are at least co-equal in importance.”). “To treat one of the . . . statutory factors in such a dramatically different fashion distorts the judgment Congress” made not to give presumptive weight to any particular factor. *American Corn Growers Ass’n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002); *see Trowell v. Beeler*, 135 F. App’x 590, 594-96 (4th Cir. 2005) (concluding that an agency abused its discretion in “ced[ing] veto power” to one statutorily mandated factors over all others).

Defendants have distorted Congress’s design by “bifurcat[ing] the [arbitrator’s] determination of the appropriate” payment rate, when it is clear “the [Subparagraph C] factors were meant to be considered together.” *American Corn Growers*, 291 F.3d, at 6. Well-established

D.C. Circuit precedent squarely forecloses this approach. In *American Corn Growers*, the court of appeals partially vacated the EPA’s Haze Rule because it “extract[ed]” one of five factors mandated by a statute (the Clean Air Act) and thereby “bifurcate[d]” the consideration of the factors. *Id.* Specifically, the EPA instructed states to treat one statutorily mandated factor differently (*i.e.*, on an area-wide basis) from their treatment of the remaining four factors (*i.e.*, on a source-by-source basis)—thus ensuring that the five factors could not be considered together, as Congress intended. The D.C. Circuit held that this “splitting of the statutory factors is consistent with neither the text nor the structure of the statute.” *Id.* So too here. The Departments’ splitting of the Subsection C factors—whereby the arbitrator must “presume” that one factor is correct, and consider the other factors only if they first meet a heightened credibility showing—also must be rejected.

A review of the full statute cinches the conclusion that the Departments’ presumption is contrary to law. Congress passed the No Surprises Act as part of the Consolidated Appropriations Act, 2021. Elsewhere in that Act, Congress expressly created a “presumption.” *See, e.g.*, Consolidated Appropriations Act, 2021, Section 226 (15 U.S.C. § 1116), “Rebuttable Presumption of Irreparable Harm” (“A plaintiff seeking any such injunction shall be entitled to a rebuttable presumption of irreparable harm upon a finding of a violation identified in this subsection[.]”). When Congress creates a presumption in one part of an Act, but “omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” *Collins v. Yellen*, 141 S. Ct. 1761, 1782 (2021) (internal quotation marks and citation omitted). Had Congress wished to make any one of the Subparagraph C Factors presumptively correct, it knew how to do so.

Third, the September Rule unlawfully constrains the discretion Congress gave to the arbitrator to weigh the Subparagraph C factors. An agency acts contrary to law when it “constrains authority Congress conferred on” a different entity. *American Corn Growers*, 291 F.3d at 9; *see Texas v. EPA*, 829 F.3d 405, 426-28 (5th Cir. 2016) (concluding that the EPA had to “defer to Texas’s [reasonable progress] goals so long as the Texas goals compl[ied] with the [Clean Air] Act” because the Act limited the EPA “to a deferential role”). Hence, in *American Corn Growers*, the D.C. Circuit held that the EPA’s Haze Rule was contrary to the Clean Air Act because the Haze Rule “tie[d] the states’ hands” by requiring them to assess one of the five statutorily mandated factors in a particular manner. This instruction contravened the statute’s “provisions giving the states broad authority over [such] determinations.” *American Corn Growers*, 291 F.3d at 8.

The September Rule similarly arrogates to the Departments discretion that Congress gave the arbitrator to determine how best to weight the Subparagraph C Factors in a given case. Congress specifically required that IDR arbitrators have “sufficient medical, legal, and other expertise” to competently assess the Subparagraph C Factors and render a payment determination in the exercise of their discretion. 42 U.S.C. § 300gg-111(c)(4)(A). By contrast, Congress gave Defendants no substantive role with respect to the arbitrator’s “[p]ayment determination.” *Id.* § 300gg-111(c)(5). This is in distinct contrast to the active role the Act gives the Departments in other provisions. *Compare id.* § 300gg-111(c)(1)(B), (2)(A), (4)(F), *with id.* § 300gg-111(c)(5). Given this clear textual division of labor, the Departments cannot now “tie the [arbitrators’] hands” with their invented presumption. *American Corn Growers*, 291 F.3d at 8.

2. *The September Rule Conflicts With The Statute’s History And Purpose*

Even when the statute’s plain meaning is clear from its terms, legislative history can help “confirm [a court’s] reading of the text.” *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 643 (D.C. Cir. 2021); *see Planned Parenthood Fed’n of Am., Inc. v. Heckler*, 712 F.2d 650, 656–57 (D.C.

Cir. 1983) (“Even when the statute’s plain meaning is clear from its terms, legislative history can be equally illuminating.” (internal quotation marks omitted)). Here, the No Surprises Act’s legislative history further demonstrates that Congress meant what it said when it required an independent arbitrator—not the Departments—to consider all of the statutory factors, without a presumption in favor of any single one.

The No Surprises Act was the result of “a long-fought and negotiated bipartisan and bicameral compromise to protect patients by ending surprise billing.” 166 Cong. Rec. H7290, H7291 (Dec. 21, 2020). Specifically, “[t]he IDR process was subject to extensive Congressional consideration for nearly two years prior to the enactment of the No Surprises Act.” Neal and Brady Letter. At the end of that process, all of the House and Senate Committee Chairmen and Ranking Members who considered different legislation on “surprise billing” issued a joint press release announcing their compromise. In it, these legislators stated:

When choosing between the two offers the arbiter is required to consider the median in-network rate, information related to the training and experience of the provider, the market share of the parties, previous contracting history between the parties, complexity of the services provided, and any other information submitted by the parties.

Press Release, House Ways & Means Comm., *Congressional Committee Leaders Announce Surprise Billing Agreement* (Dec. 11, 2020), <https://waysandmeans.house.gov/media-center/press-releases/congressional-committee-leaders-announce-surprise-billing-agreement>; see Press Release, *Senator Murray Announces Bipartisan Deal to Protect Patients, End Surprise Medical Bills* (Dec. 11, 2020), <https://www.murray.senate.gov/senator-murray-announces-bipartisan-deal-to-protect-patients-end-surprise-medical-bills/> (same).

Notably, some of these legislators originally favored legislation that looked much more like the presumption-based approach the Departments imposed in the September Rule. Many

“proposals that ultimately did not become law relied on the median in-network rate as the benchmark for payment, with baseball-style arbitration designed as a backstop to, at most, result in a mere adjustment to the benchmark rate.” Neal and Brady Letter. For example, the Lower Health Care Costs Act provided that, with certain exceptions, “[a] group health plan or health insurance issuer offering group or individual health insurance coverage *shall pay providers, including facilities and practitioners, furnishing [certain] services[,] . . . the median in-network rate* for such services.” Lower Health Care Costs Act, S. 1895, 116th Cong. § 103(a) (2019) (emphases added); *see also, e.g.*, Ban Surprise Billing Act, H.R. 5800, 116th Cong. § 2(a) (2020); No Surprises Act, H.R. 3630, 116th Cong. § 2(a) (2019). But that was *not* the compromise that Congress reached. Instead, by “provid[ing] for an IDR process overseen by an independent and neutral arbiter who must consider a number of factors equally in deciding whether to select the provider or payer’s offer,” Congress “deliberately crafted the law to avoid any one factor tipping the scales during the IDR process.” Neal and Brady Letter.

The September Rule also conflicts with Congress’s purpose. “Despite the careful balance Congress designed for the IDR process,” the September Rule “strays from the No Surprises Act in favor of an approach that Congress did not enact in the final law,” and which “essentially tips the scale for the median contracted rate being the default appropriate payment amount.” Neal and Brady Letter. It thus “affronts the provisions enacted into law” by “bias[ing] the IDR entity toward one factor (a median rate) as opposed to evaluating all factors equally as Congress intended.” *Id.* A recent letter from 150 bipartisan Members of Congress made the same point: the September Rule’s presumption-based approach for determining payment rates “do[es] not reflect the way the law was written, do[es] not reflect a policy that could have passed Congress, and do[es] not create a balanced process to settle payment disputes.” Letter from Members of Congress to Departments

Secretaries (Nov. 5, 2021), https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf. Stated simply, the Departments exceeded their statutory authority by imposing a presumption that Congress explicitly rejected.

3. The Departments' Asserted Justifications Cannot Salvage Their Unlawful Presumption

In the September Rule, the Departments defended their decision to treat the QPA in a dramatically different fashion from the other factors by raising the following heretofore unknown canons of construction: (1) “[t]he statutory text lists the QPA as the first factor,” (2) the other factors “are described in a separate paragraph” and are “subject to a prohibition on considering certain factors,” and (3) the statute “sets out detailed rules for calculating the QPA” and requires the QPA to be used in determining patient cost-sharing. 86 Fed. Reg. at 55,996. The agencies claimed that these three features rendered their reading “the best interpretation” of the statute. *Id.* It is not. Because it is a “foundational principle of administrative law” that judicial review of agency action is limited to “the grounds that the agency invoked when it took the action,” *Michigan v. EPA*, 576 U.S. 743, 758 (2015), and because these arguments are unpersuasive in light of the plain text of the statute, the Departments’ interpretation of the No Surprises Act fails on its own terms.

As an initial matter, it is important to emphasize that Defendants’ interpretation is in no way based on the text of the relevant statutory provisions. Rather, their so-called “best interpretation” is based entirely on contextual and structural features, such as the order in which the factors were listed, where those factors were located in the statute, and *other* provisions of the Act. But as Chief Justice Roberts has cautioned, “[r]eliance on context and structure in statutory interpretation is ‘a subtle business, calling for great wariness lest what professes to be mere

rendering becomes creation and attempted interpretation of legislation becomes legislation itself.” *King v. Burwell*, 576 U.S. 473, 497-98 (2015) (quoting *Palmer v. Massachusetts*, 308 U.S. 79, 83 (1939)). Just as the Chief Justice predicted, the Departments’ reliance on these contextual and structural features replaces the text of the No Surprises Act with an entirely new piece of legislation.

First, in every list of factors, one factor must be first. But that unremarkable fact has never implied that the first factor should enjoy privileged status or, on the other hand, that the last should receive inferior status. The Departments offered no authority for the proposition that the mere arrangement of statutory factors reflects congressional prioritization. On the contrary, “[n]o accepted canon of statutory interpretation permits ‘placement’ to trump text, especially where, as here, the text is clear and our reading of it is fully supported by the legislative history.” *Padilla v. Rumsfeld*, 352 F.3d 695, 721 (2d Cir. 2003), *rev’d on other grounds by Rumsfeld v. Padilla*, 542 U.S. 426 (2004).

Second, although the non-QPA factors are listed in a separate paragraph from the QPA, that does not change the fact that all of the factors are textually set forth as separate “considerations for determination.” 42 U.S.C. § 300gg-111(c)(5)(C). This would be true regardless of the Act’s paragraph placement, but it is particularly true because the non-QPA factors are expressly *incorporated in the same paragraph* as the QPA factor. *See id.* § 300gg-111(c)(5)(C)(i) (listing all the factors the arbitrator shall consider “[i]n determining which offer is the payment to be applied pursuant to *this paragraph*” (emphasis added)). The Departments’ attempt to minimize the non-QPA statutory factors because they were incorporated by reference, rather than listed directly, is precisely the kind of form-over-substance reasoning that courts have rejected.

What is more, that paragraph structure merely indicates Congress’s intent that the non-QPA factors be considered *independently* of the QPA—not dependently as the September Rule treats them. See *VirtualAgility Inc. v. Salesforce.com, Inc.*, 759 F.3d 1307, 1313 (Fed. Cir. 2014) (noting that where two factors are “listed separately in [a] statute . . . , even when both factors point in the same direction[,] . . . they continue to be separate, individual factors which must be weighed”). Indeed, where, as here, a statute mandates consideration of a factor, the factor must be independently considered even if it “has arguably [already been] considered” elsewhere. *United Parcel Serv.*, 955 F.3d at 1042. In *United Parcel Services*, the D.C. Circuit thus held that the Postal Regulatory Commission “must consider all costs uniquely or disproportionately associated with competitive products . . . even if [the Commission] has already accounted for those costs under [a different statutory provision],” and remanded the case for the Commission to do so. 955 F.3d at 1051.

Third, the Departments make far too much of the fact that the non-QPA factors may be subject to certain statutory prohibitions. Because the QPA is a set number submitted by the insurer to the arbitrator, the prohibited factors will be largely irrelevant to the QPA. There is thus little to divine from the Departments’ claim that the prohibited factors do not apply to the QPA. In fact, despite the Departments’ claim to the contrary, the prohibited factors are likewise irrelevant to the non-QPA factors. It is nonsensical to say that an arbitrator “shall not consider” certain *quantitative* factors (such as “usual and customary charges” or Medicare rates) when evaluating the *qualitative* Subparagraph C factors (such as a patient’s “acuity” or a doctor’s “experience” or an insurer’s “good faith efforts” to enter a network agreement with a provider). 42 U.S.C. § 300gg-111(c)(5)(C)(i)-(ii). In reality, the prohibited factors are far more likely to come into play in connection with an arbitrator’s consideration of “information . . . submitted by either party” or

requested by the arbitrator. *Id.* § 300gg-111(c)(5)(B), (C)(ii). And if anything, the Act’s explication of certain prohibited factors demonstrates that Congress purposely specified exactly what it wanted (and did not want) the arbitrator to consider. That the Department now uses those prohibited factors to prop up its atextual presumption reveals the frailty of its interpretation.

Fourth, it is no surprise that the Act goes into detail about how to calculate the QPA, but not other factors like a provider’s experience or a patient’s acuity. The QPA is a new concept, created entirely by the Act itself. The other factors exist independent of the Act. That Congress wanted “an accurate and clear calculation of the QPA” is not a sign that the QPA is more “integral to . . . the certified [arbitrator]’s determination of the out-of-network rate.” 86 Fed. Reg. at 55,996. All it shows is that Congress needed a few more words to explain a new statutory concept than to list straightforward, pre-existing concepts like a provider’s level of training or market share.

Finally, the Departments rely on a range of “policy considerations,” such as “increas[ing] the predictability of IDR outcomes,” “encourag[ing] parties to reach an agreement outside of the Federal IDR process to avoid the administrative costs,” and “aid[ing] in reducing prices that *may* have been inflated due to the practice of surprise billing prior to the No Surprises Act.” 86 Fed. Reg. at 55,996 (emphasis added). But “[d]isagreeing with Congress’s expressly codified policy choices isn’t a luxury administrative agencies enjoy.” *Central United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016). The Departments may not like the considered compromise Congress reached, but when Congress speaks clearly, “the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* (quoting *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984)); see *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 325 (2014) (an “agency has no power to ‘tailor’ legislation to bureaucratic policy goals by rewriting unambiguous statutory terms.”).

B. The Departments' Interpretation Of The Act's Payment Determination Provision Is Owed No Deference.

The Departments may argue that their interpretation of the Act's "Payment determination" provision is owed deference under *Chevron*, 467 U.S. 837. It is not.⁵

First, the Departments' interpretation is contrary to the Act's plain and unambiguous meaning. A court will not defer to an agency's interpretation when, after employing the "traditional tools of statutory construction," it determines that "Congress has directly spoken to the precise question at issue." *American Fuel & Petrochemical Mfrs.*, 3 F.4th at 380 (quoting *Chevron*, 467 U.S. at 843 n.9). Here, the Departments do not claim that the Act is ambiguous; they instead claim that theirs is the "best interpretation" of the Act. 86 Fed. Reg. at 55,996. But the Act includes a detailed listing of the factors an arbitrator "shall" and "shall not" consider in making a payment determination, and it delegates to the arbitrator the authority to weigh those factors and make that determination. The Act therefore unambiguously speaks to the direct question at issue: what factors the arbitrator should consider when determining which offer to select.

⁵ This is especially true in light of recent statements from Supreme Court justices casting doubt on the underpinnings of the *Chevron* doctrine. *See, e.g., Pereira v. Sessions*, 138 S. Ct. 2105, 2121 (2018) (Kennedy, J., concurring) ("It seems necessary and appropriate to reconsider, in an appropriate case, the premises that underlie *Chevron* and how courts have implemented that decision."); *Michigan*, 576 U.S. at 760 (Thomas, J., concurring) ("I write separately to note that [the agency's] request for deference raises serious questions about the constitutionality of our broader practice of deferring to agency interpretations of federal statutes."); *Gutierrez-Brizuela v. Lynch*, 834 F.3d 1142, 1149 (10th Cir. 2016) (Gorsuch, J., concurring) ("[T]he fact is *Chevron* . . . permit[s] executive bureaucracies to swallow huge amounts of core judicial and legislative power and concentrate federal power in a way that seems more than a little difficult to square with the Constitution of the framers' design. Maybe the time has come to face the behemoth."). Plaintiffs reserve the right to challenge the continuing vitality of *Chevron* should this Court conclude that Defendants are likely to prevail based on such deference.

In the September Rule, Defendants also did not claim that their invented presumption was based on either a “gap” Congress left them to fill or an express delegation regarding arbitrator payment considerations—and thus cannot do so now.⁶ See *Michigan*, 576 U.S. at 758. In any event, Congress does not create a “gap” to fill whenever it omits “thou shalt not” terms—that is, terms that expressly bar Defendants from imposing their invented presumption on the arbitrator. *American Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995). To suggest “that *Chevron* step two is implicated any time a statute does not expressly negate the existence of a claimed administrative power . . . is both flatly unfaithful to the principles of administrative law . . . , and refuted by precedent.” *Railway Labor Executives’ Ass’n v. National Mediation Bd.*, 29 F.3d 655, 671 (D.C. Cir. 1994) (*en banc*); see also *Aid Ass’n for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (“In this case, the Postal Service’s position seems to be that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency. We reject this position as entirely untenable under well-established case law.”).

Nor does the Act expressly delegate any authority to the Departments to direct the arbitrator how to determine appropriate payment rates. Congress deliberately assigned the Departments implementation roles elsewhere in the Act. For instance, the Act directs that the “Secretary [of Health and Human Services,] in consultation with the Secretary of Labor and Secretary of the

⁶ Indeed, the interim final rule does not “manifest[] its engagement in the kind of interpretive exercise to which review under *Chevron* generally applies.” *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 22 (D.C. Cir. 2019) (quoting *SoundExchange, Inc. v. Copyright Royalty Bd.*, 904 F.3d 41, 54 (D.C. Cir. 2018)). As noted, the Departments merely assert that their interpretation is the “best” one based on contextual and structural features. They do not: (1) invoke *Chevron* by name or echo its language; (2) contend that the Act is ambiguous; or (3) consider the “statutory purpose, applicable prior decisions, and the relevant legislative history.” *SoundExchange, Inc.*, 904 F.3d at 54.

Treasury, shall establish a process to certify . . . [IDR] entities under this paragraph.” 42 U.S.C. § 300gg-111(c)(4)(A). Likewise, the Act provides that, in addition to four statutorily mandated criteria, the Departments “shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity.” *Id.* § 300gg-111(c)(3)(A). Congress thus specifically delegated authority to the Departments to supplement statutorily mandated criteria found elsewhere in the Act. Yet Congress did not do the same in prescribing the Subparagraph C Factors. *See id.* § 300gg-111(c)(5)(A) (“Not later than 30 days after the date of selection of the certified IDR entity . . . the certified IDR entity shall” “taking into account the [Subparagraph C Factors]” select one of the offers.). That choice was “intentional[.]” *See Russello v. United States*, 464 U.S. 16, 23 (1983) (“Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.” (citation omitted)).⁷

⁷ The Departments cannot rely on the Act’s delegation—located in paragraph (2), not under paragraph (5)’s “Payment determination”—to “establish by regulation one independent dispute resolution process.” *See* 42 U.S.C. § 300gg-111(c)(2). By using the word “establish,” the paragraph (2) delegation gives the Departments the task of “set[ting] up” the IDR process in the first instance, not of giving the arbitrator substantive instructions with respect to her payment determination. *See* Oxford English Dictionary (defining “establish” as “To set up on a secure or permanent basis; to found (a government, an institution; in modern use often, a house of business)”); American Heritage Dictionary of the English Language (defining “establish” as “To cause (an institution, for example) to come into existence or begin operating; found; set up”). And even if the Act’s delegation to “establish” an independent dispute resolution process were broader than to simply stand up the new arbitration system, the presence of more specific delegations throughout the Act defeats any possible contention that this paragraph (2) delegation permits the Departments to impose a presumption for payment determinations. *See RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (“[T]he [general/specific] canon has full application as well to statutes such as the one here, in which a general authorization and a more limited, specific authorization exist side-by-side. There the canon avoids not contradiction but the superfluity of a specific provision that is swallowed by the general one.”).

Second, *Chevron* deference is not due when “[a] regulation is ‘procedurally defective’— that is[,] where the agency errs by failing to follow the correct procedures in issuing the regulation.” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) (quoting *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001)); see *New Hampshire Hosp. Ass’n v. Azar*, 887 F.3d 62, 76 (1st Cir. 2018) (refusing to apply *Chevron* deference under *Encino Motorcars* because “the adoption of a substantive policy in a preamble added to a regulation after notice and comment is procedurally improper”). The September Rule is “procedurally defective” because the Departments failed to provide notice and opportunity for public comment before publishing the September Rule.

The APA requires federal agencies to provide such notice and comment, unless they “for good cause” find that such procedures “are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(B). HHS Secretary Becerra in fact “guarantee[d]” that before HHS took any action on the Act, it would “take the comments necessary, hear from all the stakeholders to make sure what we’re doing is based on the facts, the science, *and the law.*” Health and Human Services Department Fiscal Year 2022 Budget Request before the House Appropriations Subcommittee (Apr. 15, 2021), <https://www.c-span.org/video/?c4980111/userclip-becerra-statements-health-human-services-budget-request> (at minute 49:06) (emphasis added). The Departments did not keep this promise. As a result, the Departments were deprived of the “expertise and input” of the parties most likely to be affected by the Rule. *National Tour Brokers Ass’n v. United States*, 591 F.2d 896, 902 (D.C. Cir. 1978).

The Departments cannot satisfy the high bar necessary to establish “good cause” here. See *Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754 (D.C. Cir. 2001) (“[T]he ‘good cause’ exception is to be narrowly construed and only reluctantly countenanced. The exception is not an

escape clause; its use should be limited to emergency situations.” (internal citations and quotation marks omitted)). With respect to the IDR process, Congress gave the Departments a full year to act. 42 U.S.C. § 300gg-111(c)(2). The Departments cannot claim exigency simply because they waited nine months to actually do so. In any event, when the Departments issued the September Rule, Congress’s deadline for establishing IDR regulations—December 27, 2021—was still three months away, and the first arbitrations were not set to begin until two months thereafter. Had the Departments promulgated the September Rule as a proposed rule and sought comment, they easily could have finalized that rule with sufficient time for the IDR process to begin in approximately March 2022.

In setting a deadline for final IDR regulations of December 27, 2021, Congress indicated that there would be sufficient time to establish the IDR process if final rules were not issued until then. In the September Rule, the Departments acknowledged this statutory deadline, but countered that “this timeframe would not provide sufficient time for the regulated entities to implement the requirements.” 86 Fed. Reg. at 56,044. Here again, the Departments have blatantly overridden Congress’s judgments, citing nothing more than a perceived need to provide guidance to insurers and providers in advance of January 1, 2022. But “good cause to suspend notice and comment must be supported by more than the bare need to have regulations.” *National Ass’n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980); *see also United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009) (“A desire to provide immediate guidance, without more, does not suffice for good cause.” (citation omitted)). Accordingly, “*Chevron* deference is not warranted” because Defendants failed “to follow the correct procedures in issuing the regulation,” and had no “good cause” for doing so. *Encino Motorcars*, 579 U.S. at 220-21.

Third, even if the No Surprises Act left some ambiguity or a gap to fill, the Departments' interpretation would be "unreasonable" in light of Congress's detailed list of factors for the arbitrator to consider (and not to consider). That list leaves no room for supplementation by the Departments. When the Departments "replaced those [multiple factors] with [a presumption] of [their] own choosing, [they] went well beyond the 'bounds of [their] statutory authority.'" *Utility Air Regulatory Grp.*, 573 U.S. at 325. Indeed, "the need to rewrite clear provisions of the statute" by inventing an extra-statutory presumption "should have alerted [the Departments] that [they] had taken a wrong interpretive turn." *Id.* at 328. The September Rule could not survive *Chevron* Step Two, if it could ever get that far.

II. PLAINTIFFS WILL SUFFER IRREPARABLE HARM ABSENT A STAY

The September Rule's presumption in favor of the QPA will irreparably harm Plaintiffs Renown Health, UMass Memorial Health, Dr. Squires, Dr. Kubit, and the other members of the AMA and AHA.

First, the September Rule will irreparably harm Plaintiff providers and the AMA's and AHA's other members when they are forced to accept unfairly low reimbursement rates as a result of the Departments' unlawful presumption. Plaintiffs' economic losses from an unfair and unlawful arbitration system will be unrecoverable from insurers because the statute expressly precludes judicial review of final and binding IDR decisions. *See* 42 U.S.C. § 300gg-111(c)(5)(E)(i)(II). Plaintiffs will also be unable to recover damages from Defendants, who enjoy sovereign immunity. 5 U.S.C. § 702 (providing for relief "other than money damages"). This renders Plaintiffs' harms "per se" irreparable. *See Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (unrecoverable harms are "per se" irreparable); *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (similar); *see also Whitman-Walker Clinic, Inc.*, 485 F. Supp. at 64-65 ("[W]here economic loss will be unrecoverable, such as in a case against a

Government defendant where sovereign immunity will bar recovery, economic loss can be irreparable' even if it would not wipe the business out." (quoting *Everglades Harvesting & Hauling, Inc. v. Scalia*, 427 F. Supp. 3d 101, 115 (D.D.C. 2019), and citing additional cases)). In addition to being "beyond remediation," these losses are irreparable because they are "certain and great" for the reasons detailed in the Rossi, Sexton, and Squires Declarations and summarized below. *Whitman-Walker Clinic, Inc.*, 485 F. Supp. 3d at 56 (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006), and *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

Second, the September Rule is *already* irreparably harming, and threatens to further harm, Plaintiff providers and the AMA and AHA's members, because it is *already* incentivizing insurers to reduce payment rates under their contracts. Because the Rule's presumption in favor of the QPA allows insurers to pay out-of-network providers at unfairly low rates, insurers can leverage the Rule to demand that in-network providers accept commensurately low rates, threatening to cancel in-network agreements if providers do not capitulate.

In fact, little more than a month after the September Rule's publication, an insurer sought to exploit the Departments' misinterpretation of the Act, to the detriment of its in-network providers and their patients. *See* BCBS Letter. Specifically, Blue Cross Blue Shield of North Carolina recently sent a letter to certain in-network providers demanding that they agree to reduced in-network rates in light of the September Rule's presumption in favor of the QPA as the appropriate payment rate. The letter states that "[w]hile the exact, final QPAs are not yet available . . . the Interim Final Rules provide enough clarity to warrant a significant reduction in your contracted rate with Blue Cross NC." *Id.* It goes on to demand "an immediate reduction in rates" to be followed by negotiation of final rates "in light of the QPA amounts established in accordance

with the upcoming Rules.” *Id.* If the provider does not agree to reduce its rates, Blue Cross Blue Shield of North Carolina will terminate its contract, thereby leaving patients with more limited coverage options than they had prior to the September Rule. *Id.* (“If we are unable to establish in-network rates more in line with a reasonable, market rate, our plan is to terminate agreements where the resulting out-of-network QPA would reduce medical expenses to the benefit of our customers’ overall premiums.”).

The attached declarations demonstrate that the September Rule’s harms are “both certain and great; . . . actual and not theoretical and of such imminence that there is a clear and present need for equitable relief.” *Olu-Cole v. Haynes Pub. Charter Sch.*, 930 F.3d 519, 529 (D.C. Cir. 2019) (citations omitted). The declaration submitted by Plaintiff Renown Health makes clear that, based on its experience with a similar regime under Nevada law, arbitrations will begin in March 2022 and they will occur frequently. *See* Sexton Decl. ¶¶ 22-25. The declaration explains the serious consequences that will occur as a result of the September Rule. It states: “This interim final rule would deliver a crippling blow to Renown’s overall reimbursement for hospital services, which we have modeled to be a minimum of 10% reduction in net reimbursement. This drop in reimbursement would drive our otherwise positive system-wide margin into an untenable net loss.” *Id.* at ¶ 26. It also explains that “[i]nsurers will likely forego negotiating longer term contracts at reasonable market rates (or will effectively do so by making unreasonable demands to arbitrarily drive reimbursement rates to below cost levels), let agreements with our hospitals lapse, and rely on this arbitration process that greatly favors them via the QPA-presumption.” *Id.* at ¶ 23. In fact, Renown notes that on December 2, 2021, one such insurer “explicitly stated [it would] no longer contract for emergency services with Renown” because of the September Rule. *Id.* at ¶ 24.

As a result of these “crippling” losses, Renown explains, it will be “even more difficult to provide the same treatments to those patients who turn to us for their healthcare needs, many of whom are the most vulnerable in our communities, be they children or those from rural parts of our state.” *Id.* at ¶¶ 26, 27; *cf. Minney v. U.S. Office of Personnel Mgmt.*, 130 F. Supp. 3d 225, 235 (D.D.C. 2015) (“The harm at issue here is irreparable in the truest sense. . . . The lapse of medical coverage caused by OPM’s failure to provide adequate advance notice is devastating for a man who is arguably more susceptible than sighted individuals to grievous physical injury. This Court is not alone in finding that a loss of this magnitude meets the litmus test for irreparable injury.”). Potential services that may be targeted for cuts include trauma, Medicaid, indigent women and children’s care, mental health services, and Renown’s children’s hospital pediatric subspecialties. *Id.* at ¶ 28. As Renown’s declarant explained: “I am gravely concerned that the negative financial implications of the QPA-presumption to Renown would leave these already-underfunded and over-burdened services with no alternative but to scale back services.” *Id.* This, in turn, will frustrate Renown Health’s mission to “make a genuine difference in the health and well-being of the people and communities [it] serve[s].” *Id.* at ¶ 29.

So too for Plaintiff UMass Memorial Health. Like Renown Health, its declaration states that the QPA-presumption “will strain UMass Memorial Health’s resources, make it more difficult for our providers to treat our patients, and thereby frustrate our non-profit health system’s statutorily-imposed mission.” Rossi Decl. ¶ 22. Specifically, based on her long experience with Blue Cross Blue Shield and recent incidents with another insurer, UMass Memorial Health’s declarant is “confident that national and local insurers in the Massachusetts market will soon similarly threaten to terminate their provider contracts if providers are unwilling to accept substantial rate reductions.” *Id.* at ¶ 25. As a result, UMass Memorial Health will receive

approximately “30% less than it otherwise would,” *id.* at ¶ 27, which is particularly damaging for a hospital that has had an average annual operating margin (1.26%) that is *half* of what experts recommend for non-profit hospitals (2.5%), *id.* at ¶¶ 19, 28. Unsurprisingly, “UMass Memorial would lose access to the resources necessary to subsidize already-underfunded services like community-based mobile medical services for indigent families and youth, food insecurity assistance care, and pediatric asthma intervention for low-income youth[.]” *Id.* at ¶ 30.

Likewise, Plaintiff Dr. Squires, an anesthesiologist who practices with Plaintiff Dr. Kubit in rural North Carolina, will suffer irreparable harm as a result of the September Rule. Based on his experience negotiating with insurers as president of his anesthesiology practice, Cumberland Anesthesia Associates, as well as his understanding of the September Rule’s presumption in favor of the QPA, Dr. Squires is “very concerned that the IDR arbitration process will routinely result in payments that are below the fair value of the out-of-network services” provided by Cumberland. Squires Decl. ¶ 9. Dr. Squires explains that the cost of anesthesia provider salaries, including for both doctors and nurses, increases substantially each year, largely due to a shortage of qualified providers in the rural area in which he practices. *Id.* at ¶ 10. A QPA tied to a 2019 lodestar and increased each year by only the consumer price index will thus “fail to adequately reflect the actual annual salaries necessary to attract talented anesthesia providers to our area.” *Id.* Accordingly, he explains that the QPA-presumption will typically result in below-fair-value payments for Cumberland’s out-of-network services, which Cumberland provides “every day” because it treats “all patients . . . regardless of their insured status or ability to pay.” *Id.* at ¶ 8. In addition, Dr. Squires expects that the September Rule will lead to undercompensation from in-network insurers, like Blue Cross Blue Shield of North Carolina, that will feel “empowered” by the QPA-presumption to demand “in-network payment rates that are far below the value of our services.”

Id. at ¶ 12. Such consistently below-fair-value payments will force Cumberland to make changes to its services, such as reducing the hours or days in which it provides anesthesia services, forcing local patients “to wait longer for surgeries or drive more than an hour to a larger city, like Raleigh, NC” for medical care. *Id.* at ¶ 11. Ultimately, Dr. Squires believes such consistent underpayments could drive small practices like Cumberland out of business, depriving local residents of much-needed medical care. *Id.* at ¶ 22.

“These harms from the forced diversion of resources are similar to those recognized as irreparable harm in other suits,” *District of Columbia v. USDA*, 444 F. Supp. 3d 1, 42 (D.D.C. 2020), and they far exceed the showing required here. Courts in this circuit have repeatedly recognized that the effects Renown Health, UMass Memorial Health, and Dr. Squires describe constitute irreparable harm. *E.g., Whitman-Walker Clinic, Inc.*, 485 F. Supp. 3d at 58 (“Because of the significant financial and operational harms the health-provider Plaintiffs will suffer on account of the 2020 Rule—and the consequent, well-established threat to their ability to deliver timely and effective care to their patients—the Court finds that their asserted injuries clear the irreparable-harm threshold.”); *Texas Children’s Hosp. v. Burwell*, 76 F. Supp. 3d 224 (D.D.C. 2014) (“Plaintiffs, moreover, are not for-profit entities facing the loss of profit; rather, they are non-profits for whom lost funds would mean reducing hospital services to children, many of whom are Medicaid-eligible. . . . While this harm would not drive plaintiffs out of business, it is different in kind from economic loss suffered by a for-profit entity.”); *see also League of Women Voters v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (finding irreparable harm when challenged action “ma[de] it more difficult for [organizations] to accomplish their primary mission”). As in those cases, the September Rule will irreparably harm both non-profit hospitals and anesthesiologists by “perceptibly impair[ing]” their “ability to provide services.” *Whitman-Walker Clinic, Inc.*, 485 F.

Supp. 3d at 56 (quoting *Food & Water Watch*, 808 F.3d 905, 919 (D.C. Cir. 2020)). What is more, “[t]he Court also [should] not turn a blind eye to the reality that here, ‘economic loss’ is not simply ‘loss of profit’; rather, it means ‘reducing [health-care] services’ to patients, many of whom are indigent.” *Id.* at 59 (quoting *Texas Children’s Hosp.*, 76 F. Supp. 3d at 243-44) (alteration in original). All in all, “the health-provider Plaintiffs’ unrecoverable future harm is of such a degree, severity, and ‘imminence that there is a clear and present need for equitable relief to prevent’ it.” *Id.* (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

Finally, the Plaintiff hospitals describe another type of well-recognized irreparable harm that they will suffer as a result of the Departments’ unlawful QPA-presumption. As noted in the Sexton and Rossi Declarations, the presumption will cause Plaintiffs and their members significant reputational harm. Both hospitals, for example, explain that their relationships with the patients and communities they serve will suffer greatly if they are forced by pervasive underpayments to either reduce some medical services or if they refuse the underpayments and thereby face termination of their contracts by insurers. *See* Sexton Decl. ¶ 29; Rossi Decl. ¶ 31. They further explain how important their reputations and relationships are to their institutions, and how both will be “irredeemably damaged” if the Rule remains in effect. *See* Sexton Decl. ¶ 29; Rossi Decl. ¶ 31. “Courts have recognized that such [reputational] harm . . . can constitute irreparable harm sufficient to qualify for a preliminary injunction.” *Everglades Harvesting*, 427 F. Supp. 3d at 116. Accordingly, even setting aside the massive economic and mission-related harms described above and in the attached declarations, Plaintiffs have amply demonstrated irreparable harm as a result of the September Rule.

To prevent this litany of irreparable harms, the Rule should be stayed.

III. THE BALANCE OF EQUITIES AND THE PUBLIC INTEREST STRONGLY FAVOR A STAY PENDING JUDICIAL REVIEW

When a stay of agency action is sought against the government, harm to the opposing party and the public interest merge into a single inquiry “because the government’s interest *is* the public interest.” *Pursuing Am.’s Greatness v. FEC*, 831 F.3d 500, 511 (D.C. Cir. 2016) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). The Court thus weighs the harm to the movants absent a stay against the impact of a stay on the government and the public interest. *Id.*

Here, the harms to movants and their patients far outweigh any potential harm to the government. The government “cannot suffer harm from [a stay] that merely ends an unlawful practice or reads a statute as required[.]” *R.I.L-R v. Johnson*, 80 F. Supp. 3d 164, 191 (D.D.C. 2015) (citation omitted); *see also League of Women Voters*, 838 F.3d at 12 (“There is generally no public interest in the perpetuation of unlawful agency action.” (collecting cases)). Rather, “there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations.” *Id.* (internal quotation marks omitted).

If that were not enough, a limited stay of the unlawful portions of the September Rule will not interfere with the IDR process because the government’s “interpretation” is not necessary for successful arbitrations under the Act. The Act already describes in detail the considerations the arbitrator should take into account in determining which offer to accept. There is thus no need for Defendants to promulgate *any* rule with respect to the arbitrator’s payment selection; Congress already gave the arbitrator all the direction she needs to select an offer. *See Public Service Co. of Indiana, Inc.*, 749 F.2d at 763 (“The *Staggers Act itself* sets certain standards that must be followed by the ICC and state commissions alike.”).

Even if there were a need for Defendants to promulgate a rule with respect to the arbitrator’s payment selection, staying the specific and limited portions of the interim final rule is

not likely to delay arbitration decisions. While the Departments dawdled in issuing their Rule, the ensuing comment period closed on December 6, 2021. *See* 86 Fed. Reg. 55,980. Thus, if they deem it necessary, the Departments would have more than enough time to publish updated final rules that conform to the Act before the first expected arbitration decisions are due in March 2022.

The public interest, meanwhile, weighs heavily in favor of a stay. Critically, the September Rule will irreparably harm the patients served by Renown Health, UMass Memorial Health, Drs. Squire and Kubit, and the other members of the AMA and AHA. As the letter from Blue Cross of North Carolina makes clear, the Rule emboldens insurers to narrow their networks and threaten to “terminate” those providers who refuse to accept unfairly low compensation rates. Other insurers are likely to take similar action. *See* Sexton Decl. ¶¶ 22-25; Rossi Decl. ¶ 25; Squires Decl. ¶¶ 17-19. The insurers’ actions will reduce the number of doctors and hospitals that are “in-network,” and thereby reduce choices and access to in-network care for patients. As explained in the attached declarations, consistent underpayments to providers will also prompt them to take measures to reduce their expected losses, such as by limiting medical services.

Finally, “[t]here is clearly a robust public interest in safeguarding prompt access to health care.” *Whitman-Walker Clinic, Inc.*, 485 F. Supp. at 61; *see New York v. DHS*, 969 F.3d 42, 87-88 (2d Cir. 2020) (finding that public interest favored preliminary injunction where agency action would likely result in worse health outcomes); *California v. Azar*, 911 F.3d 558, 582 (9th Cir. 2018) (similar). As even the Departments themselves recognize, undercompensating providers “could lead to participants, beneficiaries and enrollees not receiving needed medical care[.]” 86 Fed. Reg. at 56,044. Accordingly, the public interest will be served by staying the September Rule, leaving the arbitrators to abide by Congress’s clear and detailed instructions rather than the Departments’ atextual presumption.

CONCLUSION

For the foregoing reasons, this Court should issue as soon as possible, and before March 1, 2022, a stay pending judicial review of the provisions of the September Rule that require IDR entities to employ a presumption in favor of the offer closest to the QPA, or in the alternative, grant summary judgment in Plaintiffs' favor.

Respectfully submitted,

Dated: December 9, 2021

/s James E. Tysse

James E. Tysse
D.C. Bar No. 978722
Kelly M. Cleary
D.C. Bar No. 985642
Caroline L. Wolverton
D.C. Bar No. 496433
Daniel David Graver
D.C. Bar No. 1020026
Kristen E. Loveland (*admission pending*)
D.C. Bar No. 1684978
Akin Gump Strauss Hauer & Feld LLP
2001 K Street, N.W.
Washington, D.C. 20006
Telephone: (202) 887-4000
jtysse@akingump.com

*Counsel to Plaintiffs American Medical Association,
Stuart S. Squires, M.D., and Victor F. Kubit, M.D.*

Chad Golder
D.C. Bar No. 976914
Law Office of Chad Golder
514 6th Street, NE
Washington, DC 20002
Telephone: (203) 506-0670
golderlawoffice@gmail.com

*Counsel to Plaintiffs American Hospital Association,
Renown Health, and UMass Memorial Health Care,
Inc.*

STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

Statute

42 U.S.C. § 300gg-111.....44

Regulation

45 C.F.R. § 149.510.....47

42 U.S.C. § 300gg-111. Preventing Surprise Medical Bills

(c) Determination of out-of-network rates to be paid by health plans; independent dispute resolution process

(5) Payment determination

(A) In general

Not later than 30 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the certified IDR entity shall—

(i) taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such item or service determined under this subsection for purposes of subsection (a)(1) or (b)(1), as applicable; and

(ii) notify the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination of the offer selected under clause (i).

(B) Submission of offers

Not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination—

(i) shall each submit to the certified IDR entity with respect to such determination—

(I) an offer for a payment amount for such item or service furnished by such provider or facility; and

(II) such information as requested by the certified IDR entity relating to such offer; and

(ii) may each submit to the certified IDR entity with respect to such determination any information relating to such offer submitted by either party, including information relating to any circumstance described in subparagraph (C)(ii).

(C) Considerations in determination

(i) In general

In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider—

(I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and

(II) subject to subparagraph (D), information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

(ii) Additional circumstances

For purposes of clause (i)(II), the circumstances described in this clause are, with respect to a qualified IDR item or service of a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer of group or individual health insurance coverage the following:

(I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authorized in section 1395aaa of this title).

(II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.

(III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.

(IV) The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.

(V) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Prohibition on consideration of certain factors

In determining which offer is the payment to be applied with respect to qualified IDR items and services furnished by a provider or facility, the certified IDR entity with respect to a determination shall not consider usual and customary charges, the amount that would have been billed by such provider or facility with respect to such items and services had the provisions of section 300gg-131 or section 300gg-132 of this title (as applicable) not applied, or the payment or reimbursement rate for such items and services furnished by such provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act, under the Medicaid program under title XIX of such Act, under the Children's Health Insurance Program under title XXI of such Act, under the TRICARE program under chapter 55 of Title 10, or under chapter 17 of Title 38.

45 C.F.R. § 149.510. Independent Dispute Resolution Process

(a) Scope and definitions—

(2) Definitions

(v) Credible information means information that upon critical analysis is worthy of belief and is trustworthy.

(viii) Material difference means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.

(c) Federal IDR process following initiation—

(4) Payment determination for a qualified IDR item or service—

(i) Submission of offers. Not later than 10 business days after the selection of the certified IDR entity, the plan or issuer and the provider, facility, or provider of air ambulance services:

(A) Must each submit to the certified IDR entity:

(1) An offer of an out-of-network rate expressed as both a dollar amount and the corresponding percentage of the qualifying payment amount represented by that dollar amount;

(2) Information requested by the certified IDR entity relating to the offer.

(3) The following additional information, as applicable—

(i) For providers and facilities, information on the size of the provider's practice or of the facility (if applicable). Specifically, a group of providers must specify whether the providers' practice has

fewer than 20 employees, 20 to 50 employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees. For facilities, the facility must specify whether the facility has 50 or fewer employees, 51 to 100 employees, 101 to 500 employees, or more than 500 employees;

(ii) For providers and facilities, information on the practice specialty or type, respectively (if applicable);

(iii) For plans and issuers, information on the coverage area of the plan or issuer, the relevant geographic region for purposes of the qualifying payment amount, whether the coverage is fully-insured or partially or fully self-insured (or a FEHB carrier if the item or service relates to FEHB plans); and

(iv) The qualifying payment amount for the applicable year for the same or similar item or service as the qualified IDR item or service.

(B) May each submit to the certified IDR entity any information relating to the offer that was submitted by either party, except that the information may not include information on factors described in paragraph (c)(4)(v) of this section.

(ii) Payment determination and notification. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions. In these cases, the certified IDR entity must select the offer as the out-of-network rate that the certified IDR entity determines best represents the value of the qualified IDR item or services, which could be either offer.

(iii) Considerations in determination. In determining which offer to select, the certified IDR entity must consider:

(A) The qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) Information requested by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section relating to the offer, to the extent a party provides credible information.

(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

(1) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished the qualified IDR item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act).

(2) The market share held by the provider or facility or that of the plan or issuer in the geographic region in which the qualified IDR item or service was provided.

(3) The acuity of the participant, beneficiary, or enrollee receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee.

(4) The teaching status, case mix, and scope of services of the facility that furnished the qualified IDR item or service, if applicable.

(5) Demonstration of good faith efforts (or lack thereof) made by the provider or facility or the plan or issuer to enter into network agreements with each other, and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Additional information submitted by a party, provided the information is credible and relates to the offer submitted by either party and does not include information on factors described in paragraph (c)(4)(v) of this section.

(vi) Written decision.

(A) The certified IDR entity must explain its determination in a written decision submitted to the parties and the Secretary, in a form and manner specified by the Secretary;

(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.