No. 23-40217

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

Texas Medical Association; Tyler Regional Hospital, L.L.C.; Doctor Adam Corley,
Plaintiffs-Appellees,

v.

United States Department of Health and Human Services; Department of Labor; Department of the Treasury; Xavier Becerra, Secretary, U.S. Department of Health and Human Services; Julie A. Su, Acting Secretary, U.S. Department of Labor; Janet Yellen, Secretary, U.S. Department of Treasury,
Defendants-Appellants.

LifeNet, Incorporated; East Texas Air One,
Plaintiffs-Appellees,

v.

United States Department of Health and Human Services; Xavier Becerra, Secretary, U.S. Department of Health and Human Services; United States Department of the Treasury; Janet Yellen, Secretary, U.S. Department of Treasury; United States Department of Labor; Julie A. Su, Acting Secretary, U.S. Department of Labor; United States Office of Personnel Management; Kiran Ahuja,
Defendants-Appellants.

On Appeal from the United States District Court
for the Eastern District of Texas

RECORD EXCERPTS

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TAB 1

(Docket Entries, *Texas Medical Association v. HHS*)

APPEAL,LEAD

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U.S. District Court
Eastern District of TEXAS [LIVE] (Tyler)
CIVIL DOCKET FOR CASE #: 6:22-cv-00372-JDK

Texas Medical Association et al v. United States Department of Health and Human Services et al
Assigned to: District Judge Jeremy D. Kernodle
Related Case: 6:22-cv-00453-JDK
Case in other court: USCA, 5th Cir., 23-40217
Cause: 05:551 Administrative Procedure Act

Date Filed: 09/22/2022
Date Terminated: 02/06/2023
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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Date Filed	#	Docket Text
09/22/2022	1 (p.24)	COMPLAINT *FOR DECLARATORY AND INJUNCTIVE RELIEF* against DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, United States Department of Health and Human Services (Filing fee $ 402 receipt number ATXEDC-9142058.), filed by Adam Corley. (Attachments: # 1 (p.24) Civil Cover Sheet)(Reid, Penny) (Entered: 09/22/2022)
09/22/2022		District Judge Jeremy D. Kernodle added. (wea,) (Entered: 09/23/2022)
09/23/2022		In accordance with the provisions of 28 USC Section 636(c), you are hereby notified that a U.S. Magistrate Judge of this district court is available to conduct any or all proceedings in this case including a jury or non-jury trial and to order the entry of a final judgment. The form Consent to Proceed Before Magistrate Judge is available on our website. All signed consent forms, excluding pro se parties, should be filed electronically using the event *Notice Regarding Consent to Proceed Before Magistrate Judge*. (wea,) (Entered: 09/23/2022)
09/27/2022	2 (p.54)	SUMMONS Issued as to Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, United States Department of Health and Human Services, Martin J. Walsh, and Janet Yellen. (Attachments: # 1 (p.24) Summons(es), # 2 (p.54) Summons(es), # 3 (p.66) Summons(es), # 4 (p.77) Summons(es), # 5 (p.81) Summons(es))(ndc) (Entered: 09/27/2022)
09/30/2022	3 (p.66)	Joint MOTION to Consolidate Cases *6:22-cv-00372 and 6:22-cv-00373*, Joint MOTION to Expedite *Summary Judgment Briefing Schedule* by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Attachments: # 1 (p.24) Exhibit 1 - Proposed Order to Consolidate, # 2 (p.54) Exhibit 2 - Proposed Order to Set Expedited Summary Judgment Briefing Schedule)(Reid, Penny) (Entered: 09/30/2022)
10/04/2022	4 (p.77)	CORPORATE DISCLOSURE STATEMENT filed by Texas Medical Association (Reid, Penny) (Entered: 10/04/2022)
10/04/2022	5 (p.81)	CORPORATE DISCLOSURE STATEMENT filed by Tyler Regional Hospital, LLC identifying Corporate Parent East Texas Health System, LLC, Corporate Parent AHS East Texas Health System, LLC and University of Texas Health Science Center at Tyler for Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/04/2022)
10/04/2022	6 (p.85)	ORDER granting 3 (p.66) Motion to Consolidate Cases *6:22-cv-00372 and 6:22-cv-00373*. It is ORDERED that these two cases are CONSOLIDATED, with Case No. 6:22-cv-372 as the lead case. All future docket entries should be made only in the lead case except for orders reflecting a final disposition. Signed by District Judge Jeremy D. Kernodle on 10/4/2022. (wea,) (Entered: 10/04/2022)

10/04/2022	7 (p.87)	ORDER ON SUMMARY JUDGMENT BRIEFING AND SETTING HEARING. The Court hereby GRANTS in part the parties' 3 (p.66) Joint MOTION to Expedite Summary Judgment Briefing Schedule. The Court hereby sets the parties' summary judgment motions for an in-person hearing on **12/20/2022 at 9:30 AM** in Ctrm 101 (Tyler) before District Judge Jeremy D. Kernodle. Signed by District Judge Jeremy D. Kernodle on 10/4/2022. (wea,) (Entered: 10/04/2022)
10/04/2022	8 (p.89)	NOTICE of Attorney Appearance - Pro Hac Vice by Brenna E Jenny on behalf of All Plaintiffs. Filing fee $ 100, receipt number ATXEDC-9163238. (Jenny, Brenna) (Entered: 10/04/2022)
10/04/2022	9 (p.91)	NOTICE of Attorney Appearance - Pro Hac Vice by Jaime L.M. Jones on behalf of All Plaintiffs. Filing fee $ 100, receipt number ATXEDC-9163254. (Jones, Jaime) (Entered: 10/04/2022)
10/04/2022	10 (p.93)	NOTICE of Attorney Appearance - Pro Hac Vice by Eric D McArthur on behalf of All Plaintiffs. Filing fee $ 100, receipt number ATXEDC-9163277. (McArthur, Eric) (Entered: 10/04/2022)
10/05/2022	11 (p.96)	SUMMONS Returned Executed by Lifenet, Inc.. Janet Yellen served on 9/30/2022, answer due 10/21/2022. (Shepard, Steven) (Entered: 10/05/2022)
10/05/2022	12 (p.98)	SUMMONS Returned Executed by Lifenet, Inc.. Xavier Becerra served on 10/3/2022, answer due 10/24/2022. (Shepard, Steven) (Entered: 10/05/2022)
10/05/2022	13 (p.100)	SUMMONS Returned Executed by Lifenet, Inc.. U.S. Department of the Treasury served on 10/3/2022, answer due 12/02/2022. (Shepard, Steven). (Entered: 10/05/2022)
10/05/2022	14 (p.102)	NOTICE of Attorney Appearance by Anna L Deffebach on behalf of All Defendants (Deffebach, Anna) (Entered: 10/05/2022)
10/05/2022	15 (p.104)	SUMMONS Returned Executed by Lifenet, Inc.. U.S. Department of Labor served on 9/29/2022, answer due 11/28/2022. (Shepard, Steven). (Entered: 10/05/2022)
10/05/2022	16 (p.106)	AFFIDAVIT of Service for Summons, Civil Cover Sheet, Original Complaint, Exhibit A and Plaintiff's Rule 7.1 Corporate Disclosure Statement served on Merrick B. Garland, Attorney General of the U.S. on October 3, 2022, filed by Lifenet, Inc.. (Shepard, Steven). (Entered: 10/05/2022)
10/05/2022	17 (p.108)	SUMMONS Returned Executed by Lifenet, Inc.. U.S. Office of Personnel Management served on 9/29/2022, answer due 11/28/2022. (Shepard, Steven). (Entered: 10/05/2022)
10/05/2022	18 (p.110)	SUMMONS Returned Executed by Lifenet, Inc.. Martin J. Walsh served on 10/3/2022, answer due 10/24/2022. (Shepard, Steven) (Entered: 10/05/2022)
10/05/2022	19 (p.112)	SUMMONS Returned Executed by Lifenet, Inc.. Kiran Ahuja served on 10/3/2022, answer due 10/24/2022. (Shepard, Steven) (Entered: 10/05/2022)
10/05/2022	20 (p.114)	SUMMONS Returned Executed by Lifenet, Inc. U.S. Department of Health and Human Services served on 10/3/2022, answer due 12/02/2022. (Shepard, Steven). (Entered: 10/05/2022)
10/05/2022	21 (p.116)	AFFIDAVIT of Service for Summons, Civil Cover Sheet, Original Complaint, Exhibit A and Plaintiff's Rule 7.1 Corporate Disclosure Statement served on US Attorney's Office for the Eastern District of Texas on September 29, 2022, filed by

		Lifenet, Inc.. (Shepard, Steven). (Entered: 10/05/2022)
10/05/2022	22 (p.118)	NOTICE of Attorney Appearance - Pro Hac Vice by Madeleine Joseph on behalf of All Plaintiffs. Filing fee $ 100, receipt number ATXEDC-9165029. (Joseph, Madeleine) (Entered: 10/05/2022)
10/06/2022	23 (p.120)	NOTICE of Attorney Appearance - Pro Hac Vice by Steven M. Shepard on behalf of Lifenet, Inc.. Filing fee $ 100, receipt number ATXEDC-9166241. (Shepard, Steven) (Additional attachment(s) added on 10/6/2022: # 1 (p.24) Sealed Attachment) (nkl,). (Entered: 10/06/2022)
10/06/2022		***DOCKETED IN ERROR. PLEASE DISREGARD.*** NOTICE of Deficiency regarding the Affidavits of Service, 16 (p.106) and 21 (p.116) submitted. Incorrect docketing event. To be refiled as Summons Returned Executed. (wea,). (Entered: 10/06/2022)
10/06/2022	24	***PLEASE DISREGARD. AFFIDAVIT FILED AT 16 (p.106) *** SUMMONS Returned Executed by Lifenet, Inc. (Shepard, Steven) Modified on 10/7/2022 (wea,). (Entered: 10/06/2022)
10/06/2022	25	***PLEASE DISREGARD. AFFIDAVIT FILED AT 21 (p.116) *** SUMMONS Returned Executed by Lifenet, Inc. (Shepard, Steven) Modified on 10/7/2022 (wea,). (Entered: 10/06/2022)
10/07/2022	26 (p.122)	NOTICE of Designation of Attorney in Charge to Eric D McArthur on behalf of Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC (McArthur, Eric) (Entered: 10/07/2022)
10/11/2022	27	***FILED IN ERROR BY ATTORNEY*** SUMMONS Returned Executed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. DEPARTMENT OF THE TREASURY served on 10/4/2022, answer due 10/25/2022. (Reid, Penny) Modified on 10/12/2022 (gsm). (Entered: 10/11/2022)
10/11/2022	28	***FILED IN ERROR BY ATTORNEY*** SUMMONS Returned Executed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. DEPARTMENT OF LABOR served on 10/6/2022, answer due 10/27/2022. (Reid, Penny) Modified on 10/12/2022 (gsm). (Entered: 10/11/2022)
10/11/2022	29	***FILED IN ERROR BY ATTORNEY*** SUMMONS Returned Executed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. United States Department of Health and Human Services served on 10/3/2022, answer due 10/24/2022. (Reid, Penny) Modified on 10/12/2022 (gsm). (Entered: 10/11/2022)
10/11/2022	30 (p.125)	AFFIDAVIT of Service for Complaint for Declaratory and Injunctive Relief served on United States Attorney for the Eastern District of Texas on 9/28/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	31 (p.126)	AFFIDAVIT of Service for Summonses for each named defendant and Complaint for Declaratory and Injunctive Relief served on United States Attorney General on 10/4/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	32 (p.128)	NOTICE of Attorney Appearance - Pro Hac Vice by Eric David Chan on behalf of Physicians Advocacy Institute, American Association of Neurological Surgeons, Congress of Neurological Surgeons. Filing fee $ 100, receipt number

		ATXEDC-9172048. (Chan, Eric) (Entered: 10/11/2022)
10/11/2022	33 (p.130)	AFFIDAVIT of Service for Summons and Complaint for Declaratory and Injunctive Relief served on United States Department of the Treasury on 10/4/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	34 (p.132)	AFFIDAVIT of Service for Summons and Complaint for Declaratory and Injunctive Relief served on United States Department of Labor on 10/6/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	35 (p.134)	AFFIDAVIT of Service for Summons and Complaint for Declaratory and Injunctive Relief served on United States Department of Health and Human Services c/o Office of the General Counsel on 10/3/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	36 (p.136)	AFFIDAVIT of Service for Summons and Complaint for Declaratory and Injunctive Relief served on Janet Yellen, Secretary of the United States Department of the Treasury, in her official capacity only on 10/4/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	37 (p.138)	AFFIDAVIT of Service for Summons and Complaint for Declaratory and Injunctive Relief served on Martin J. Walsh, Secretary of the United States Depaitment of Labor, in his official capacity only on 10/6/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	38 (p.140)	AFFIDAVIT of Service for Summons and Complaint for Declaratory and Injunctive Relief served on Xavier Becerra, Secretary of the United States Department of Health and Human Services, in his official capacity only on 10/3/22, filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Reid, Penny) (Entered: 10/11/2022)
10/11/2022	39 (p.142)	NOTICE of Attorney Appearance - Pro Hac Vice by Joseph R LoCascio on behalf of All Plaintiffs. Filing fee $ 100, receipt number ATXEDC-9173005. (LoCascio, Joseph) (Entered: 10/11/2022)
10/12/2022	40 (p.144)	NOTICE of Attorney Appearance - Pro Hac Vice by Long Xuan Do on behalf of American Association of Neurological Surgeons, Congress of Neurological Surgeons, Physicians Advocacy Institute. Filing fee $ 100, receipt number ATXEDC-9173992. (Do, Long) (Entered: 10/12/2022)
10/12/2022	41 (p.146)	MOTION for Summary Judgment *And Memorandum In Support Thereof* by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC. (Attachments: # 1 (p.24) Exhibit A, # 2 (p.54) Exhibit B, # 3 (p.66) Exhibit C, # 4 (p.77) Exhibit D, # 5 (p.81) Text of Proposed Order)(McArthur, Eric) (Additional attachment(s) added on 10/12/2022: # 6 (p.85) Revised Proposed Order) (gsm,). (Entered: 10/12/2022)
10/12/2022	42 (p.212)	MOTION for Summary Judgment *and Memorandum in Support* by Lifenet, Inc.. (Attachments: # 1 (p.24) Exhibit E - Declaration of Joan E. Davanzo, # 2 (p.54) Exhibit F - Declaration of James Craig Smyser, # 3 (p.66) Exhibit G - Declaration of James L. Gaines, # 4 (p.77) Text of Proposed Order)(Shackelford, Stephen) (Entered: 10/12/2022)

10/12/2022	43 (p.291)	MOTION to Seal Document *Exhibit 1 to Gaines Declaration [dkt 42-3]* by Lifenet, Inc.. (Attachments: # 1 (p.24) Exhibit 1 - Redacted Exh 1 to Gaines Declaration, # 2 (p.54) Text of Proposed Order)(Shepard, Steven) (Entered: 10/12/2022)
10/12/2022	44	SEALED ADDITIONAL ATTACHMENTS to Main Document: 43 (p.291) MOTION to Seal Document *Exhibit 1 to Gaines Declaration [dkt 42-3].* *(Attachments: # 1 (p.24) Exhibit 1 - Sealed Exh 1 to Gaines Declaration)(Shepard, Steven) (Entered: 10/12/2022)*
10/14/2022	45 (p.299)	NOTICE of Attorney Appearance - Pro Hac Vice by Ronald S. Connelly on behalf of American Society of Anesthesiologists, American College of Emergency Physicians, American College of Radiology. Filing fee $ 100, receipt number ATXEDC-9180200. (Connelly, Ronald) (Entered: 10/14/2022)
10/18/2022	46 (p.301)	NOTICE of Attorney Appearance - Pro Hac Vice by James Tysse on behalf of American Medical Association, American Hospital Association. Filing fee $ 100, receipt number ATXEDC-9185171. (Tysse, James) (Entered: 10/18/2022)
10/18/2022	47 (p.304)	NOTICE of Attorney Appearance - Pro Hac Vice by Kelly M. Cleary on behalf of American Hospital Association, American Medical Association. Filing fee $ 100, receipt number ATXEDC-9185238. (Cleary, Kelly) (Entered: 10/18/2022)
10/18/2022	48 (p.307)	NOTICE of Attorney Appearance - Pro Hac Vice by Kristen Loveland on behalf of American Hospital Association, American Medical Association. Filing fee $ 100, receipt number ATXEDC-9185268. (Loveland, Kristen) (Entered: 10/18/2022)
10/19/2022	49 (p.310)	NOTICE of Attorney Appearance - Pro Hac Vice by Jack R. Bierig on behalf of The Emergency Department Practice Management Association. Filing fee $ 100, receipt number ATXEDC-9187336. (Bierig, Jack) (Entered: 10/19/2022)
10/19/2022	50 (p.312)	NOTICE of Attorney Appearance by Catherine Susan Bartles on behalf of The Emergency Department Practice Management Association (Bartles, Catherine) (Entered: 10/19/2022)
10/19/2022	51 (p.314)	BRIEF filed *Amicus Curiae Brief In Support Of Plaintiffs Motion For Summary Judgment* by Physicians Advocacy Institute. (Do, Long) (Entered: 10/19/2022)
10/19/2022	52 (p.341)	NOTICE of Attorney Appearance by Stafford Grigsby Helm Davis on behalf of The Emergency Department Practice Management Association (Davis, Stafford) (Entered: 10/19/2022)
10/19/2022	53 (p.343)	BRIEF filed *(amicus)* by American College of Emergency Physicians, American College of Radiology, American Society of Anesthesiologists. (Attachments: # 1 (p.24) Exhibit (Schedule of), # 2 (p.54) Exhibit A. Nicola Declaration, # 3 (p.66) Exhibit B. Young Declaration, # 4 (p.77) Exhibit C. Raley Declaration)(Connelly, Ronald) (Entered: 10/19/2022)
10/19/2022	54 (p.381)	BRIEF filed *Amicus* by American Hospital Association, American Medical Association. (Tysse, James) (Entered: 10/19/2022)
10/19/2022	55 (p.408)	BRIEF filed *Amicus Brief* by The Emergency Department Practice Management Association. (Attachments: # 1 (p.24) Exhibit 1, # 2 (p.54) Exhibit 2, # 3 (p.66) Exhibit 3, # 4 (p.77) Exhibit 4, # 5 (p.81) Exhibit 5, # 6 (p.85) Exhibit 6, # 7 (p.87) Exhibit 7, # 8 (p.89) Exhibit 8, # 9 (p.91) Exhibit 9, # 10 (p.93) Exhibit 10, # 11 (p.96) Exhibit 11, # 12 (p.98) Exhibit 12, # 13 (p.100) Exhibit 13, # 14 (p.102) Exhibit 14, # 15 (p.104) Exhibit 15, # 16 (p.106) Exhibit 16, # 17 (p.108) Exhibit

		17)(Bierig, Jack) (Entered: 10/19/2022)
10/19/2022	56 (p.527)	CORPORATE DISCLOSURE STATEMENT filed by The Emergency Department Practice Management Association (Bierig, Jack) (Entered: 10/19/2022)
10/20/2022	57 (p.529)	CORPORATE DISCLOSURE STATEMENT filed by American College of Emergency Physicians, American College of Radiology, American Society of Anesthesiologists (Connelly, Ronald) (Entered: 10/20/2022)
10/20/2022	58 (p.531)	CORPORATE DISCLOSURE STATEMENT filed by American Hospital Association, American Medical Association (Tysse, James) (Entered: 10/20/2022)
10/21/2022	59 (p.534)	CORPORATE DISCLOSURE STATEMENT filed by Physicians Advocacy Institute (Do, Long) (Entered: 10/21/2022)
11/03/2022	60 (p.537)	Joint MOTION for Leave to File *Joint Appendix Containing Relevant Portions of the Administrative Record* by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen. (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 11/03/2022)
11/04/2022	61 (p.544)	ORDER granting in part 60 (p.537) Motion for Leave. The parties are ORDERED to file a joint appendix containing copies of those portions of the administrative record that are cited or otherwise relied upon in any memorandum in support of or in opposition to any dispositive motion by December 14, 2022. Signed by District Judge Jeremy D. Kernodle on 11/4/2022. (wea,) (Entered: 11/04/2022)
11/09/2022	62 (p.545)	RESPONSE in Opposition re 41 (p.146) MOTION for Summary Judgment *And Memorandum In Support Thereof*, 42 (p.212) MOTION for Summary Judgment *and Memorandum in Support filed by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen*. (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 11/09/2022)
11/09/2022	63 (p.599)	Cross MOTION for Summary Judgment by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen. (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 11/09/2022)
11/10/2022	64 (p.653)	AMENDED COMPLAINT against Kiran Ahuja, Xavier Becerra, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, Martin J. Walsh, Janet Yellen, filed by Lifenet, Inc., East Texas Air One. (Attachments: # 1 (p.24) Exhibit 1-Redline of the Original Complaint, # 2 (p.54) Exhibit 2- Declaration of John A. Smith)(Shepard, Steven) (Entered: 11/10/2022)
11/10/2022		

	65 (p.730)	CORPORATE DISCLOSURE STATEMENT filed by East Texas Air One (Shepard, Steven) (Entered: 11/10/2022)
11/10/2022	66 (p.732)	NOTICE by East Texas Air One, Lifenet, Inc. re 42 (p.212) MOTION for Summary Judgment *and Memorandum in Support Notice of Joinder by East Texas Air One to Lifenet's Motion for Summary Judgment* (Shepard, Steven) (Entered: 11/10/2022)
11/11/2022	67 (p.734)	NOTICE of Attorney Appearance by Stephen Lee Shackelford, Jr on behalf of East Texas Air One (Shackelford, Stephen) (Entered: 11/11/2022)
11/11/2022	68 (p.735)	NOTICE of Attorney Appearance by Steven M. Shepard on behalf of East Texas Air One (Shepard, Steven) (Entered: 11/11/2022)
11/14/2022	69 (p.736)	NOTICE of Attorney Appearance - Pro Hac Vice by James Craig Smyser on behalf of East Texas Air One, Lifenet, Inc.. Filing fee $ 100, receipt number ATXEDC-9224538. (Smyser, James) (Entered: 11/14/2022)
11/15/2022	70 (p.738)	NOTICE of Attorney Appearance - Pro Hac Vice by Ryan Temme on behalf of American Benefits Council, Business Group on Health, Council of Insurance Agents and Brokers, DFW Business Group on Health, ERISA Industry Committee, Houston Business Coalition on Health, HR Policy Association, National Alliance of Health Care Purchaser Coalitions, National Retail Federation, Purchaser Business Group on Health, Self-Insurance Institute of America, Texas Business Group on Health, Texas Employers for Affordable Healthcare. Filing fee $ 100, receipt number ATXEDC-9226954. (Temme, Ryan) (Entered: 11/15/2022)
11/15/2022	71 (p.740)	NOTICE of Attorney Appearance - Pro Hac Vice by Seth T Perretta on behalf of American Benefits Council, Business Group on Health, Council of Insurance Agents and Brokers, DFW Business Group on Health, ERISA Industry Committee, HR Policy Association, Houston Business Coalition on Health, National Alliance of Health Care Purchaser Coalitions, National Retail Federation, Purchaser Business Group on Health, Self-Insurance Institute of America, Texas Business Group on Health, Texas Employers for Affordable Healthcare. Filing fee $ 100, receipt number ATXEDC-9227125. (Perretta, Seth) (Entered: 11/15/2022)
11/15/2022	72 (p.742)	NOTICE of Attorney Appearance - Pro Hac Vice by Joseph J Wardenski on behalf of Leukemia & Lymphoma Society, Hemophilia Federation of America, CancerCare, United States Public Interest Research Group, Inc., National Multiple Sclerosis Society, Epilepsy Foundation, Families USA Action, ALS Association. Filing fee $ 100, receipt number ATXEDC-9227663. (Wardenski, Joseph) (Entered: 11/15/2022)
11/15/2022	73 (p.744)	NOTICE of Attorney Appearance - Pro Hac Vice by Hyland Hunt on behalf of America's Health Insurance Plans. Filing fee $ 100, receipt number ATXEDC-9228939. (Hunt, Hyland) (Entered: 11/15/2022)
11/16/2022	74 (p.747)	BRIEF filed *(Amicus Curiae)* by American Benefits Council, Business Group on Health, Council of Insurance Agents and Brokers, DFW Business Group on Health, ERISA Industry Committee, HR Policy Association, Houston Business Coalition on Health, National Alliance of Health Care Purchaser Coalitions, National Retail Federation, Purchaser Business Group on Health, Self-Insurance Institute of America, Texas Business Group on Health, Texas Employers for Affordable Healthcare. (Perretta, Seth) (Entered: 11/16/2022)
11/16/2022	75 (p.771)	CORPORATE DISCLOSURE STATEMENT filed by American Benefits Council, Business Group on Health, Council of Insurance Agents and Brokers, DFW

		Business Group on Health, ERISA Industry Committee, HR Policy Association, Houston Business Coalition on Health, National Alliance of Health Care Purchaser Coalitions, National Retail Federation, Purchaser Business Group on Health, Self-Insurance Institute of America, Texas Business Group on Health, Texas Employers for Affordable Healthcare (Perretta, Seth) (Entered: 11/16/2022)
11/16/2022	76 (p.773)	BRIEF filed *Amicus Curiae Brief* by America's Health Insurance Plans. (Hunt, Hyland) (Entered: 11/16/2022)
11/16/2022	77 (p.791)	CORPORATE DISCLOSURE STATEMENT filed by America's Health Insurance Plans (Hunt, Hyland) (Entered: 11/16/2022)
11/16/2022	78 (p.793)	BRIEF filed *as Amici Curiae in Support of Defendants* by ALS Association, CancerCare, Epilepsy Foundation, Families USA Action, Hemophilia Federation of America, Leukemia & Lymphoma Society, National Multiple Sclerosis Society, United States Public Interest Research Group, Inc., Cancer Support Community. (Attachments: # 1 (p.24) Exhibit A - Surprise Medical Billing Coalition Principles)(Wardenski, Joseph) (Entered: 11/16/2022)
11/16/2022	79 (p.822)	CORPORATE DISCLOSURE STATEMENT filed by ALS Association, Cancer Support Community, CancerCare, Epilepsy Foundation, Families USA Action, Hemophilia Federation of America, Leukemia & Lymphoma Society, National Multiple Sclerosis Society, United States Public Interest Research Group, Inc. (Wardenski, Joseph) (Entered: 11/16/2022)
11/17/2022	80 (p.825)	NOTICE of Attorney Appearance - Pro Hac Vice by Max I Straus on behalf of East Texas Air One, Lifenet, Inc.. Filing fee $ 100, receipt number ATXEDC-9232029. (Straus, Max) (Entered: 11/17/2022)
11/21/2022	81 (p.827)	MOTION to Strike 64 (p.653) Amended Complaint, by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen. (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 11/21/2022)
11/23/2022	82 (p.840)	RESPONSE in Opposition re 63 (p.599) Cross MOTION for Summary Judgment *And Reply In Support Of Motion For Summary Judgment filed by Adam Corley, Texas Medical Association, Tyler Regional Hospital, LLC*. (Attachments: # 1 (p.24) Text of Proposed Order)(McArthur, Eric) (Entered: 11/23/2022)
11/23/2022	83 (p.880)	RESPONSE in Opposition re 63 (p.599) Cross MOTION for Summary Judgment *and Reply Brief in Support of Motion for Summary Judgment filed by East Texas Air One, Lifenet, Inc.*. (Attachments: # 1 (p.24) Declaration of Steven M. Shepard, # 2 (p.54) Exhibit 1)(Shepard, Steven) (Additional attachment(s) added on 11/29/2022: # 3 (p.66) Text of Proposed Order) (wea,). (Entered: 11/23/2022)
12/06/2022	84 (p.908)	RESPONSE in Opposition re 81 (p.827) MOTION to Strike 64 (p.653) Amended Complaint, *Motion in the Alternative, For Leave To File Amended Complaint filed by East Texas Air One, Lifenet, Inc.*. (Attachments: # 1 (p.24) Declaration of Steven M. Shepard, # 2 (p.54) Text of Proposed Order)(Shepard, Steven) (Entered: 12/06/2022)
12/07/2022	85 (p.921)	ORDER Setting Hearing on Summary Judgment Motions. Hearing set for **12/20/2022 at 9:30 AM** before District Judge Jeremy D. Kernodle.. Signed by

		District Judge Jeremy D. Kernodle on 12/7/2022. (wea,). (Entered: 12/07/2022)
12/07/2022	86 (p.922)	REPLY to Response to Motion re 63 (p.599) Cross MOTION for Summary Judgment *filed by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen*. (Deffebach, Anna) (Entered: 12/07/2022)
12/13/2022	87 (p.957)	REPLY to Response to Motion re 81 (p.827) MOTION to Strike 64 (p.653) Amended Complaint, *and Opposition to LifeNet's Motion in the Alternative for Leave to File Amended Complaint filed by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen*. (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 12/13/2022)
12/13/2022	88 (p.966)	NOTICE by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen *of Filing of Joint Appendix* (Attachments: # 1 (p.24) Appendix Joint Appendix Part 1, # 2 (p.54) Appendix Joint Appendix Part 2)(Deffebach, Anna) (Entered: 12/13/2022)
12/16/2022	89 (p.1797)	REPLY to Response to Motion re 81 (p.827) MOTION to Strike 64 (p.653) Amended Complaint, *filed by East Texas Air One, Lifenet, Inc.*. (Straus, Max) (Entered: 12/16/2022)
12/20/2022	90 (p.1804)	Minute Entry for proceedings held before District Judge Jeremy D. Kernodle: Motion Hearing held on 12/20/2022 re 41 (p.146) MOTION for Summary Judgment *And Memorandum In Support Thereof* filed by Tyler Regional Hospital, LLC, Texas Medical Association, Adam Corley, 42 (p.212) MOTION for Summary Judgment *and Memorandum in Support* filed by Lifenet, Inc., 63 (p.599) Cross MOTION for Summary Judgment filed by U.S. Office of Personnel Management, DEPARTMENT OF LABOR, Martin J. Walsh, DEPARTMENT OF THE TREASURY, U.S. Department of Labor, Janet Yellen, U.S. Department of Health and Human Services, United States Department of Health and Human Services, Xavier Becerra, Kiran Ahuja, U.S. Department of the Treasury. (9:30 am - 10:39 am) Attorney Appearances: Plaintiff - Eric D. McArthur, Steven M. Shepard, Madeleine Joseph; Defense - Anna L. Deffebach. (No exhibits)(Court Reporter Shea Sloan) (esw) (Entered: 12/20/2022)
12/20/2022	91 (p.1805)	ORDER denying 81 (p.827) Motion to Strike Amended Complaint and, to the extent necessary, GRANTS Plaintiffs' motion for leave to amend 84 (p.908) . Plaintiffs' Amended Complaint is accepted as filed 64 (p.653) . The parties are ORDERED to meet and confer and file a proposed briefing schedule on any new issues raised by the Amended Complaint by **December 23, 2022**. Signed by District Judge Jeremy D. Kernodle on 12/20/2022. (wea,) (Entered: 12/20/2022)
12/21/2022	92 (p.1807)	PAPER TRANSCRIPT REQUEST by Texas Medical Association for proceedings held on 12/20/2022 before Judge Jeremy Kernodle. (Reid, Penny)(Forwarded to

		Court Reporter, Shea Sloan, on 12/21/2022)(slo) (Entered: 12/21/2022)
12/22/2022	93 (p.1809)	NOTICE by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen *Joint Response to ECF 91 Proposing Briefing Schedule* (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 12/22/2022)
12/22/2022	94 (p.1874)	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Motions Hearing Proceedings held on 12/20/2022 before Judge Jeremy D. Kernodle. Court Reporter: Shea Sloan, shea_sloan@txed.uscourts.gov. NOTICE RE REDACTION OF TRANSCRIPTS: The parties have seven (7) days to file with the Court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will be made remotely electronically available to the public without redaction after 90 calendar days. The policy is located on our website at www.txed.uscourts.gov. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER.. Motion to Redact due 1/12/2023. Release of Transcript Restriction set for 3/22/2023. (sms,) (Entered: 12/22/2022)
12/28/2022	95 (p.1814)	SCHEDULING ORDER. No further briefing will be considered without leave of the Court. Signed by District Judge Jeremy D. Kernodle on 12/28/2022. (wea,) (Entered: 12/28/2022)
01/19/2023	96 (p.1815)	Cross MOTION for Summary Judgment *and Opposition to East Texas Air One's Motion for Summary Judgment* by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen. (Attachments: # 1 (p.24) Text of Proposed Order)(Deffebach, Anna) (Entered: 01/19/2023)
02/03/2023	97 (p.1827)	REPLY to Response to Motion re 96 (p.1815) Cross MOTION for Summary Judgment *and Opposition to East Texas Air One's Motion for Summary Judgment East Texas Air One's Supplemental Reply in Support of Summary Judgment & Supplemental Opposition to Defendant's Cross-Motion for Summary Judgment filed by East Texas Air One*. (Shepard, Steven) (Entered: 02/03/2023)
02/06/2023	98 (p.1836)	ORDER granting 43 (p.291) Motion to Seal Document *Exhibit 1 to Gaines Declaration [dkt 42-3]*. Signed by District Judge Jeremy D. Kernodle on 2/6/2023. (wea,) (Entered: 02/06/2023)
02/06/2023	99 (p.1837)	MEMORANDUM OPINION AND ORDER. The Court GRANTS Plaintiffs TMA, Dr. Adam Corley, and Tyler Regional Hospital's motion for summary judgment 41 (p.146) , GRANTS Plaintiffs LifeNet and East Texas Air One's motion for summary judgment 42 (p.212) , DENIES Defendants' cross-motions for summary judgment 63 (p.599) , 96 (p.1815) , and ORDERS provisions of the Final Rule are VACATED and REMANDED for further consideration. Signed by District Judge Jeremy D. Kernodle on 2/6/2023. (wea,) (Entered: 02/06/2023)
02/06/2023		

	100 (p.1869)	FINAL JUDGMENT. All relief not expressly granted herein is DENIED. Any pending motions are DENIED as MOOT. The Clerk of Court is instructed to close these consolidated cases. Signed by District Judge Jeremy D. Kernodle on 2/6/2023. (wea,) (Entered: 02/06/2023)
04/06/2023	101 (p.1871)	NOTICE OF APPEAL as to 99 (p.1837) Memorandum & Opinion, 100 (p.1869) Judgment by Kiran Ahuja, Xavier Becerra, Xavier Becerra, DEPARTMENT OF LABOR, DEPARTMENT OF THE TREASURY, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, United States Department of Health and Human Services, Martin J. Walsh, Martin J. Walsh, Janet Yellen, Janet Yellen. (Deffebach, Anna) (Entered: 04/06/2023)
04/17/2023		NOTICE of Docketing Notice of Appeal from USCA re 101 (p.1871) Notice of Appeal, filed by U.S. Office of Personnel Management, DEPARTMENT OF LABOR, Martin J. Walsh, DEPARTMENT OF THE TREASURY, U.S. Department of Labor, Janet Yellen, U.S. Department of Health and Human Services, United States Department of Health and Human Services, Xavier Becerra, Kiran Ahuja, U.S. Department of the Treasury. USCA Case Number 23-40217 (wea,) (Entered: 04/24/2023)

TAB 2

(Docket Entries, *LifeNet, Inc. v. HHS*)

APPEAL,CONSOL

Jump to Docket Table

U.S. District Court
Eastern District of TEXAS [LIVE] (Tyler)
CIVIL DOCKET FOR CASE #: 6:22-cv-00373-JDK

Lifenet, Inc. v. U.S. Department of Health and Human Services et al
Assigned to: District Judge Jeremy D. Kernodle
Related Case: 6:22-cv-00453-JDK
Cause: 05:551 Administrative Procedure Act

Date Filed: 09/23/2022
Date Terminated: 02/06/2023
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

Plaintiff

Lifenet, Inc.

represented by **Steven M. Shepard**
Susman Godrey LLP - New York
1301 Avenue of the Americas, 32nd Floor
New York, NY 10019-6022
212-729-2010
Fax: 212-336-8340
Email: sshepard@susmangodfrey.com
ATTORNEY TO BE NOTICED

V.

Defendant

U.S. Department of Health and Human Services

represented by **Anna L Deffebach**
Department of Justice, Civil Div, Federal Programs Branch
1100 L. Street NW, Room 12312
Washington, DC 20005
202-305-8356
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ATTORNEY TO BE NOTICED

Defendant

Xavier Becerra

represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

U.S. Department of the Treasury

represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

Janet Yellen represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

U.S. Department of Labor represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

Martin J Walsh represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

U.S. Office of Personnel Management represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Defendant

Kiran Ahuja represented by **Anna L Deffebach**
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
09/23/2022	1 (p.2002)	COMPLAINT *for Declaratory and Injunctive Relief* against All Defendants (Filing fee $ 402 receipt number ATXEDC-9145112.), filed by Lifenet, Inc.. (Attachments: # 1 (p.2002) Civil Cover Sheet)(Shepard, Steven) (Entered: 09/23/2022)
09/23/2022	2 (p.2041)	CORPORATE DISCLOSURE STATEMENT filed by Lifenet, Inc. (Shepard, Steven) (Entered: 09/23/2022)
09/26/2022	3 (p.2042)	SUMMONS Issued as to Kiran Ahuja, Xavier Becerra, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, Martin J Walsh, Janet Yellen. (Attachments: # 1 (p.2002) Summons(es), # 2 (p.2041) Summons(es), # 3 (p.2042) Summons(es), # 4 (p.2058) Summons(es), # 5 (p.2160) Summons(es), # 6 (p.2162) Summons(es), # 7 (p.2164) Summons(es))(ndc) (Entered: 09/26/2022)
09/26/2022	4 (p.2058)	Additional Attachments to Main Document: 1 (p.2002) Complaint.. (Shepard, Steven) (Entered: 09/26/2022)
09/27/2022		District Judge Jeremy D. Kernodle added. (gsm) (Entered: 09/27/2022)
10/04/2022	5 (p.2160)	ORDER OF CONSOLIDATION. It is ORDERED that these two cases are CONSOLIDATED, with Case No. 6:22-cv-372 as the lead case. All future docket entries should be made only in the lead case except for orders reflecting a final disposition. Signed by District Judge Jeremy D. Kernodle on 10/4/2022. (wea,) (Entered: 10/04/2022)

10/04/2022		**This civil action is CONSOLIDATED with cause 6:22-cv-372 designated as the Lead Case. All future pleadings are to be filed in the Lead Case.** (wea,) (Entered: 10/04/2022)
02/06/2023	6 (p.2162)	FINAL JUDGMENT. All relief not expressly granted herein is DENIED. Any pending motions are DENIED as MOOT. The Clerk of Court is instructed to close these consolidated cases. Signed by District Judge Jeremy D. Kernodle on 2/6/2023. (wea,) (Entered: 02/06/2023)
04/06/2023	7 (p.2164)	NOTICE OF APPEAL as to 6 (p.2162) Judgment by Kiran Ahuja, Xavier Becerra, U.S. Department of Health and Human Services, U.S. Department of Labor, U.S. Department of the Treasury, U.S. Office of Personnel Management, Martin J Walsh, Janet Yellen. (Deffebach, Anna) (Entered: 04/06/2023)
04/06/2023	8 (p.2167)	NOTICE of Attorney Appearance by Anna L Deffebach on behalf of All Defendants (Deffebach, Anna) (Entered: 04/06/2023)

TAB 3

(Notice of Appeal, *Texas Medical Association v. HHS*)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 6:22-cv-00372-JDK Lead Consolidated Case

NOTICE OF APPEAL

PLEASE TAKE NOTICE that all Defendants—the United States Department of Health and Human Services; the United States Department of the Treasury; the United States Department of Labor; the Office of Personnel Management; Xavier Becerra, in his official capacity as the Secretary of Health and Human Services; Janet Yellen, in her official capacity as the Secretary of the Treasury; Julie Su, in her official capacity as the Acting Secretary of Labor[1]; and Kiran Ahuja, in her official capacity as the Director of the Office of Personnel Management—hereby appeal to the United States Court of Appeals for the Fifth Circuit from the Memorandum Opinion and Order (ECF No. 99) granting summary judgment to the Plaintiffs and denying summary judgment to the Defendants, entered in this action on February 6, 2023; from the Final Judgment (ECF No. 100) in favor of the Plaintiffs, entered in this action on the same date; and from all previous rulings in these consolidated actions.

Dated: April 6, 2023

Respectfully submitted,

[1] *See* Fed. R. Civ. P. 25(d).

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

BRIT FEATHERSTON
United States Attorney

ERIC B. BECKENHAUER
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Counsel for Defendants

TAB 4

(Notice of Appeal, *LifeNet, Inc. v. HHS*)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

LIFENET, INC., *et al.*, Plaintiffs, v. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 6:22-cv-00373-JDK No. 6:22-cv-00372-JDK Lead Consolidated Case

NOTICE OF APPEAL

PLEASE TAKE NOTICE that all Defendants—the United States Department of Health and Human Services; the United States Department of the Treasury; the United States Department of Labor; the Office of Personnel Management; Xavier Becerra, in his official capacity as the Secretary of Health and Human Services; Janet Yellen, in her official capacity as the Secretary of the Treasury; Julie Su, in her official capacity as the Acting Secretary of Labor[1]; and Kiran Ahuja, in her official capacity as the Director of the Office of Personnel Management—hereby appeal to the United States Court of Appeals for the Fifth Circuit from the Memorandum Opinion and Order in the Lead Consolidated Case, *Texas Medical Association v. U.S. Department of Health & Human Services*, No. 6:22-cv-372, ECF No. 99 (E.D. Tex. Feb. 6, 2023), granting summary judgment to the Plaintiffs and denying summary judgment to the Defendants, entered in this action on February 6, 2023; from the Final

[1] *See* Fed. R. Civ. P. 25(d).

Judgment entered in this case (ECF No. 6) in favor of the Plaintiffs on the same date; and from all previous rulings in these consolidated actions.

Dated: April 6, 2023

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

BRIT FEATHERSTON
United States Attorney

ERIC B. BECKENHAUER
Assistant Branch Director

/s/ Anna Deffebach
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Counsel for Defendants

TAB 5

(Final Judgment, *Texas Medical Association v. HHS*)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	§ § § § § § § § § § § § §	Case No. 6:22-cv-372-JDK
LIFENET, INC., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	§ § § § § § § § § § § § §	Case No. 6:22-cv-373-JDK

FINAL JUDGMENT

Pursuant to the Court's Memorandum Opinion and Order (Docket No. 99) granting Plaintiffs' Motions for Summary Judgment and denying Defendants' Cross-Motions for Summary Judgment, and for the reasons stated therein, the Court hereby enters Final Judgment in favor of Plaintiffs Texas Medical Association, Dr. Adam Corley, Tyler Regional Hospital, LLC, LifeNet, Inc., and East Texas Air One and against Defendants United States Department of Health and Human Services,

United States Department of Labor, United States Department of the Treasury, United States Office of Personnel Management, and current heads of those agencies in their official capacities, Xavier Becerra, Janet Yellen, Martin J. Walsh, and Kiran Ahuja as follows:

The Court **ORDERS** that the following provisions of the Final Rule are **VACATED** and **REMANDED** for further consideration:

(1) The word "then" in 45 C.F.R. § 149.510(c)(4)(iii)(B); the entirety of 45 C.F.R. §§ 149.510(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 45 C.F.R. § 149.510(c)(4)(vi)(B);

(2) The word "then" in 26 C.F.R. § 54.9816-8(c)(4)(iii)(B); the entirety of 26 C.F.R. § 54.9816-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 26 C.F.R. § 54.9816-8(c)(4)(vi)(B);

(3) The word "then" in 29 C.F.R. § 2590-716-8(c)(4)(iii)(B); the entirety of 29 C.F.R. § 2590-716-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 29 C.F.R. § 2590-716-8(c)(4)(vi)(B);

(4) The entirety of 45 C.F.R. § 149.520(b)(3);

(5) The entirety of 26 C.F.R. § 54.9817-2(b)(3); and

(6) The entirety of 29 C.F.R. § 2590-717-2(b)(3).

All relief not expressly granted herein is **DENIED**. Any pending motions are **DENIED** as **MOOT**. The Clerk of Court is instructed to close these consolidated cases.

So **ORDERED** and **SIGNED** this **6th** day of **February, 2023.**

JEREMY D. KERNODLE
UNITED STATES DISTRICT JUDGE

TAB 6

(Final Judgment, *LifeNet, Inc. v. HHS*)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	§ § § § § § § § § § § § §	Case No. 6:22-cv-372-JDK
LIFENET, INC., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	§ § § § § § § § § § § § §	Case No. 6:22-cv-373-JDK

FINAL JUDGMENT

Pursuant to the Court's Memorandum Opinion and Order (Docket No. 99) granting Plaintiffs' Motions for Summary Judgment and denying Defendants' Cross-Motions for Summary Judgment, and for the reasons stated therein, the Court hereby enters Final Judgment in favor of Plaintiffs Texas Medical Association, Dr. Adam Corley, Tyler Regional Hospital, LLC, LifeNet, Inc., and East Texas Air One and against Defendants United States Department of Health and Human Services,

United States Department of Labor, United States Department of the Treasury, United States Office of Personnel Management, and current heads of those agencies in their official capacities, Xavier Becerra, Janet Yellen, Martin J. Walsh, and Kiran Ahuja as follows:

The Court **ORDERS** that the following provisions of the Final Rule are **VACATED** and **REMANDED** for further consideration:

(1) The word "then" in 45 C.F.R. § 149.510(c)(4)(iii)(B); the entirety of 45 C.F.R. §§ 149.510(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 45 C.F.R. § 149.510(c)(4)(vi)(B);

(2) The word "then" in 26 C.F.R. § 54.9816-8(c)(4)(iii)(B); the entirety of 26 C.F.R. § 54.9816-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 26 C.F.R. § 54.9816-8(c)(4)(vi)(B);

(3) The word "then" in 29 C.F.R. § 2590-716-8(c)(4)(iii)(B); the entirety of 29 C.F.R. § 2590-716-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 29 C.F.R. § 2590-716-8(c)(4)(vi)(B);

(4) The entirety of 45 C.F.R. § 149.520(b)(3);

(5) The entirety of 26 C.F.R. § 54.9817-2(b)(3); and

(6) The entirety of 29 C.F.R. § 2590-717-2(b)(3).

All relief not expressly granted herein is **DENIED**. Any pending motions are **DENIED** as **MOOT**. The Clerk of Court is instructed to close these consolidated cases.

So **ORDERED** and **SIGNED** this **6th** day of **February, 2023.**

JEREMY D. KERNODLE
UNITED STATES DISTRICT JUDGE

TAB 7

(Memorandum Opinion and Order)

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

TEXAS MEDICAL ASSOCIATION, et al.,	§	
Plaintiffs,	§	
	§	Case No. 6:22-cv-372-JDK
v.	§	
	§	Lead Consolidated Case
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

In these consolidated cases, Plaintiff providers challenge portions of a final rule (the "Final Rule") issued by the Defendant Departments under the No Surprises Act (the "Act"). The Final Rule governs the arbitration process for resolving payment disputes between certain out-of-network providers and group health plans and health insurance issuers.

In two prior cases, the Court addressed the Act and reviewed an interim final rule issued by the Departments governing the arbitration process. The Court first held that the Act unambiguously requires arbitrators to consider several factors when selecting the proper payment amount—and does not instruct arbitrators to weigh any one factor or circumstance more heavily than the others.[1] The Court then concluded

[1] *See Tex. Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 587 F. Supp. 3d 528 (E.D. Tex. 2022), *appeal dismissed*, 2022 WL 15174345 (5th Cir. Oct. 24, 2022) [hereinafter *TMA*]; *LifeNet, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 2022 WL 2959715 (E.D. Tex. July 26, 2022).

that the interim rule conflicted with the Act because it improperly restricted arbitrators' discretion and directed them to consider one factor—the qualifying payment amount, or "QPA"—as more important than the others. Indeed, when drafting the interim rule, the Departments had publicly expressed concern that arbitrators would select higher payment amounts favored by providers, resulting in higher healthcare costs. The interim rule therefore imposed a "rebuttable presumption" that the offer closest to the QPA should be chosen. This, the Departments explained, would "have a downward impact on health care costs" by lowering payment amounts to providers.[2] Providers challenged the interim rule, and the Court vacated certain provisions, including the rebuttable presumption in favor of the QPA, after determining that the provisions conflicted with the Act.

The Departments went back to the drawing board. In August 2022, they issued the Final Rule at issue here, replacing the provisions vacated in the prior cases with new requirements for arbitrators when considering the statutory factors. Plaintiffs now challenge these requirements and argue that they unlawfully conflict with the Act in the same manner as the vacated provisions in the interim rule—they improperly restrict arbitrators' discretion and unlawfully tilt the arbitration process in favor of the QPA. The Court agrees.

Accordingly, for the reasons discussed below, the Court concludes that the challenged portions of the Final Rule are unlawful and must be set aside under the Administrative Procedure Act ("APA"). The Court **GRANTS** Plaintiffs' motions for

[2] Requirements Related to Surprise Billing; Part II, 86 Fed. Reg. 55,980, 56,060 (Oct. 7, 2021).

summary judgment (Docket Nos. 41, 42) and **DENIES** the Departments' cross-motions for summary judgment (Docket Nos. 63, 96).

I.

In the No Surprises Act, Congress established an arbitration process for resolving disputes between out-of-network providers and insurers, detailing the information arbitrators may consider in determining the proper payment amount. Citing the Act, the Departments issued an interim final rule limiting how arbitrators may consider that information—which this Court held unlawful under the APA. The Departments then issued the Final Rule that is the subject of these consolidated cases.

A.

Congress enacted the No Surprises Act in December 2020 to address "surprise medical bills." Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758–2890 (2020). Generally, the Act limits the amount an insured patient will pay for emergency services furnished by an out-of-network provider and for certain non-emergency services furnished by an out-of-network provider at an in-network facility. 42 U.S.C. §§ 300gg-111, 300gg-131, 300gg-132.[3]

The Act also addresses the payment of these out-of-network providers by group health plans or health insurance issuers (collectively, "insurers"). In particular, the Act requires insurers to reimburse out-of-network providers at a statutorily

[3] The Act amended three statutes: the Public Health Service Act ("PHSA") (administered by the Department of Health and Human Services), the Employee Retirement Income Security Act ("ERISA") (administered by the Department of Labor), and the Internal Revenue Code (administered by the Department of the Treasury). For ease of reference, this Opinion cites to the PHSA.

calculated "out-of-network rate." § 300gg-111(a)(1)(C)(iv)(II), (b)(1)(D). In states with an All-Payer Model Agreement or specified state law, the out-of-network rate is the rate provided by the Model Agreement or state law. § 300gg-111(a)(3)(K). In states without a Model Agreement or specified state law, the out-of-network rate is either the amount agreed to by the insurer and the out-of-network provider or an amount determined through an independent dispute resolution ("IDR") process. *Id.*

When an insured receives certain out-of-network medical services, insurers must issue an initial payment or notice of denial of payment to a provider within thirty days after the provider submits a bill for that service. § 300gg-111(a)(1)(C)(iv), (b)(1)(C). If the provider disagrees with the insurer's determination, the provider may initiate a thirty-day period of open negotiation with the insurer over the claim. § 300gg-111(c)(1)(A). If the parties cannot resolve the dispute through negotiation, the parties may then proceed to IDR arbitration. § 300gg-111(c)(1)(B).

The IDR process—which is the subject of this lawsuit—is a "baseball-style" arbitration. The provider and insurer each submits a proposed payment amount and explanation to the arbitrator. § 300gg-111(c)(5)(B). The arbitrator must then select one of the two proposed payment amounts "taking into account the considerations specified in subparagraph (C)." § 300gg-111(c)(5)(A). Subparagraph C states as follows:

> (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 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.

§ 300gg-111(c)(5)(C).

The Act also prohibits the arbitrator from considering the provider's usual and customary charges for an item or service, the amount the provider would have billed

for the item or service in the absence of the Act, or the reimbursement rates for the item or service under the Medicare, Medicaid, Children's Health Insurance, or Tricare programs. § 300gg-111(c)(5)(D). The arbitrator's selection of a payment amount is binding on the parties, and is not subject to judicial review, except under the circumstances described in the Federal Arbitration Act. § 300gg-111(c)(5)(E).

Important to the challenge here is "the qualifying payment amount" ("QPA"), referenced in § 300gg-111(c)(5)(C)(i)(I). The QPA is generally "the median of the contracted rates recognized by the plan or issuer . . . under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item[s] or service is furnished," with annual increases based on the consumer price index. § 300gg-111(a)(3)(E)(i)(I)-(II). In other words, the QPA is typically the median rate the insurer would have paid for the service if provided by an in-network provider or facility. Notably, insurers are charged by regulation to calculate the QPA. § 300gg-111(a)(3)(E)(i)(I).

The Act also implements a parallel IDR process for determining payments to out-of-network providers of air ambulance services, which largely incorporates by reference the IDR process discussed above. § 300gg-112(b)(4)(A) (citing § 300gg-111(c)(4)). The additional circumstances the arbitrator must "tak[e] into account" for air-ambulance providers differ slightly from those listed above in ways not relevant to the present litigation. *Compare* § 300gg-112(b)(5)(C)(ii), *with* § 300gg-111(c)(5)(C)(ii).

Finally, the Act requires the Secretaries of Health and Human Services, Labor, and the Treasury (collectively, the "Departments") to "establish by regulation one independent dispute resolution process (referred to in this subsection as the 'IDR process') under which . . . a certified IDR entity . . . determines, subject to subparagraph (B) and in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility." § 300gg-111(c)(2)(A); *accord* § 300gg-112(b)(2)(A).

B.

On September 30, 2021, the Departments issued an interim final rule implementing the IDR process. Requirements Related to Surprise Billing: Part II, 86 Fed. Reg. 55,980 (Oct. 7, 2021).

Under the interim rule, the arbitrator was required to select the proposed payment amount closest to the QPA unless certain conditions were satisfied. 45 C.F.R. § 149.510(c)(4)(ii).[4] Specifically, the interim rule required arbitrators to "select the offer closest to the [QPA]" unless "credible" information, including information supporting the "additional factors," "clearly demonstrates that the [QPA] is materially different from the appropriate out-of-network rate." § 149.510(c)(4)(ii)(A). The Departments explained at the time that the interim rule effectively created a "rebuttable presumption" that the amount closest to the QPA was the proper payment amount. *See* 86 Fed. Reg. 56,056–61. And because the QPA is "typically lower than

[4] As with the Act, identical interim final rules appeared in three separate sections of the C.F.R., specifically Title 45 – Public Health, Title 26 – Internal Revenue, and Title 29 – Labor. For ease of reference, this Opinion cites to Title 45.

billed charges," the Departments reasoned, the interim rule would ensure arbitrators routinely select the offer favoring the insurers. *Id*. at 56,056–61.

Multiple providers challenged the interim rule under the APA. *See TMA*, 587 F. Supp. 3d at 536; *LifeNet, Inc.*, 2022 WL 2959715. The providers argued that the interim rule required arbitrators to give "outsized weight" to the QPA in conflict with the Act. *TMA*, 587 F. Supp. 3d at 536; *LifeNet, Inc.*, 2022 WL 2959715, at *3. The QPA, the providers contended, does not "accurately reflect [the providers'] cost of providing services in most cases." *TMA*, 587 F. Supp. 3d at 538. For example, the QPA fails to consider patient acuity, which poses a significant problem for providers who "treat the patients in the sickest lines of service at [] Level I Trauma Center[s]." *See, e.g.*, Declaration of Dr. Dao at 4, *TMA*, No. 6:21-cv-425 (E.D. Tex. Jan. 24, 2022), ECF No. 98, Ex. 2. The providers thus argued that the interim rule would "systematically reduce out-of-network reimbursement," *TMA*, 587 F. Supp. 3d at 537, and "threaten the viability" of many providers' practices, Declaration of Dr. Cook at 5, *TMA*, No. 6:21-cv-425 (E.D. Tex. Jan. 24, 2022), ECF No. 98, Ex. 1. Indeed, some providers stated that insurers had terminated their contracts in anticipation of the interim rule because the providers would not agree to "deflated rate[s]" for their services. Declaration of Dr. Ford at 4, *TMA*, No. 6:21-cv-425 (E.D. Tex. Jan. 24, 2022), ECF No. 98, Ex. 3. The providers also argued that the interim rule was issued without the required notice and comment under the APA. *TMA*, 587 F. Supp. 3d at 543; *LifeNet, Inc.*, 2022 WL 2959715, at *9.

The Court largely agreed. *TMA*, 587 F. Supp. 3d at 549; *LifeNet, Inc.*, 2022 WL 2959715, at *10. The Court first held that the interim rule improperly "places its thumb on the scale for the QPA, requiring arbitrators to presume the correctness of the QPA and then imposing a heightened burden on the remaining statutory factors to overcome the presumption." *TMA*, 587 F. Supp. 3d at 542. The interim rule, moreover, characterized the non-QPA factors as "permissible additional factors" that an arbitrator may consider only "when appropriate." *Id.* (quoting 86 Fed. Reg. at 56,080). The interim rule thus conflicted with the Act, which unambiguously requires arbitrators to consider "all the specified information in determining which offer to select" and nowhere instructs them "to weigh any one factor or circumstance more heavily than the others." *Id.* at 541 (citing *Am. Corn Growers Ass'n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002) (holding that where "no weights were assigned" to statutory factors, "treat[ing] one of the five statutory factors in such a dramatically different fashion distorts the judgment Congress directed")); *accord LifeNet, Inc.*, 2022 WL 2959715, at *10. The Act, moreover, does not "impose a 'rebuttable presumption' that the offer closest to the QPA should be chosen—or suggest anywhere that the other factors or information is less important than the QPA." *TMA*, 587 F. Supp. 3d at 541. Because the interim final rule conflicted with the Act, the Court held it unlawful and set it aside under the APA. *Id.* at 543 (citing *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014); and 5 U.S.C. § 706(2)(A)); *LifeNet, Inc.*, 2022 WL 2959715, at *9.

The Court also held that the Departments violated the APA by failing to provide the required notice and comment. *TMA*, 587 F. Supp. 3d at 543–48 (citing 5

U.S.C. § 553(b), (c) (requiring agencies to publish a "notice of proposed rule making" and "give interested persons an opportunity to participate . . . through submission of written data, views, or arguments")); *LifeNet, Inc.*, 2022 WL 2959715, at *9. This failure "provide[d] a second and independent basis" to set aside the challenged provisions of the interim final rule. *TMA*, 587 F. Supp. 3d at 548; *LifeNet, Inc.*, 2022 WL 2959715, at *9.

C.

In August 2022, the Departments issued the Final Rule at issue here. Requirements Related to Surprise Billing, 87 Fed. Reg. 52,618 (Aug. 26, 2022). Although the Departments "remove[d] from the regulations the language vacated" in *TMA* and *LifeNet, Inc.*, *id.* at 52,625, the Final Rule still limits the discretion of arbitrators in determining the payment amount. This time, the Departments were more circumspect in explaining why they wanted to limit arbitrators' discretion, stating only that the Departments seek greater predictability in payment outcomes. *See* 87 Fed. Reg. at 52,634.

The Final Rule requires arbitrators to consider the QPA first and only "then consider" the non-QPA factors, as set forth in relevant part below:

> (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, weighing only 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 that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

. . . .

(iii) Considerations in determination. In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(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.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(2) of this section that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

45 C.F.R. § 149.510(c)(4).[5] The Rule, moreover, requires arbitrators to presume the credibility of the QPA while "evaluat[ing]" the credibility of the non-QPA factors. Indeed, the Rule prohibits arbitrators from "giv[ing] weight to" the non-QPA factors unless certain prerequisites are met:

> (E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

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[5] The Final Rule for payment disputes involving out-of-network air ambulance providers, 45 C.F.R. § 149.520(b)(1), incorporates "the requirements of § 149.510," "[e]xcept as provided in paragraphs (b)(2) and (3)." Paragraph (b)(2) lists the following non-QPA factors for arbitrators to consider:

> (2) Considerations for air ambulance services. In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:
> (i) The quality and outcomes measurements of the provider that furnished the services.
> (ii) The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.
> (iii) The training, experience, and quality of the medical personnel that furnished the air ambulance services.
> (iv) Ambulance vehicle type, including the clinical capability level of the vehicle.
> (v) Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).
> (vi) Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer, as applicable, during the previous 4 plan years.

§ 149.520(b)(2). Paragraph (b)(3) states the prerequisites for "giv[ing] weight to" non-QPA factors. § 149.520(b)(3). These prerequisites are identical to those found in § 149.510(c)(4)(iii)(E), except for minor differences in wording not relevant here. Owing to the similarity, the Departments cite only to § 149.510. For ease of reference, this Opinion will do the same.

§ 149.510(c)(4)(iii)(E). Finally, the Final Rule imposes an additional writing requirement on arbitrators who give weight to any non-QPA factor:

> (vi) Written decision.
>
> . . . .
>
> (B) . . . . If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

§ 149.510(c)(4)(vi).

D.

Plaintiffs are healthcare and air ambulance service providers.[6] In two cases consolidated here, they challenge the Final Rule under the APA on two grounds. First, Plaintiffs argue that the Rule "exceed[s] the Departments' statutory authority and conflict[s] with the [Act]" by limiting arbitrators' discretion in considering the statutory factors and by making the QPA "the *de facto* benchmark for out-of-network reimbursement." Docket No. 41 at 15; *accord* Docket No. 42 at 9 (incorporating "by reference the merits argument set forth in TMA's brief" which "apply in full to air ambulance providers"). Plaintiffs also assert that the Final Rule is arbitrary and

[6] Plaintiffs in the lead consolidated case (Civil No. 6:22-cv-372) are the Texas Medical Association, a trade association representing more than 56,000 Texas physicians and medical students; Dr. Adam Corley, a Tyler, Texas physician; and Tyler Regional Hospital, LLC, a hospital in Tyler, Texas, that provides emergency services as defined in the Act. Docket No. 1 ¶¶ 12–14. Both Dr. Corley and the Texas Medical Association previously challenged the interim final rule. *TMA*, 587 F. Supp. 3d at 536. Plaintiffs in the consolidated case (Civil No. 6:22-cv-373) are two air ambulance service providers, LifeNet, Inc., and East Texas Air One, LLC. Docket No. 64 ¶¶ 10–11. LifeNet previously challenged the interim final rule's provisions for air ambulance service providers. *LifeNet, Inc.*, 2022 WL 2959715, at *1.

capricious because it "flunks the APA's fundamental requirements of reasoned decisionmaking." Docket No. 41 at 15; *accord* Docket No. 42 at 9.

Accordingly, Plaintiffs request that the Court vacate certain provisions of the Rule—namely, 45 C.F.R. § 149.510(c)(4)(iii)(A)–(B), § 149.510(c)(4)(iii)(E), § 149.510(c)(4)(iv), and § 149.510(c)(4)(vi). Docket No. 1 ¶ 56. Plaintiffs LifeNet and East Texas Air One also seek to vacate § 149.520(b)(3). Docket No. 64 at ¶¶ 54, 99.[7] Plaintiffs further request the Court to remand these provisions to the Departments "with specific instructions" that they promulgate a new rule that complies with the Act. Docket No. 41 at 30; Docket No. 42 at 16.

Defendants are the Departments responsible for promulgating the Final Rule—the Departments of Health and Human Services, Labor, and the Treasury, along with the Office of Personnel Management and the current heads of those agencies in their official capacities. Docket No. 1 ¶¶ 11–18. Together, the Departments contend that the Final Rule is consistent with the Act. Docket No. 63.

Both sides now move for summary judgment under Federal Rule of Civil Procedure 56. Docket Nos. 41, 42, 63, 96. Summary judgment is proper when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–25 (1986); *Ragas v. Tenn. Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998).

[7] After entering the case, East Texas Air One joined LifeNet's summary judgment motion. Docket No. 66.

Both sides agree that the Court can determine Plaintiffs' APA challenge as a matter of law.

II.

The Departments first argue that Plaintiffs lack standing to challenge the Final Rule because their alleged injuries are speculative.[8] The Departments also argue that LifeNet lacks standing because Air Methods Corporation, not insurers, pays LifeNet for its services—an argument the Court rejected in *LifeNet, Inc.*, 2022 WL 2959715, at *5–8.

As explained below, the Court concludes that Plaintiffs have demonstrated two cognizable injuries resulting from the Final Rule and that the Departments' additional argument regarding LifeNet is without merit.

A.

"The irreducible minimum constitutional standing requirement to invoke a federal court's Article III jurisdiction is (1) injury-in-fact (2) fairly traceable to the defendant's actions and (3) likely to be redressed by a favorable decision." *Ensley v. Cody Res., Inc.*, 171 F.3d 315, 319 (5th Cir. 1999) (citing *Raines v. Byrd*, 521 U.S. 811, 818 (1997); *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982)). "For standing purposes," the Court must

[8] The Departments assert these arguments against all Plaintiffs. Docket No. 63 at 17 ("Plaintiffs have not adequately shown that they have standing . . . ."). While East Texas Air One joined the case as a plaintiff later than the other parties, the Departments present identical standing arguments against East Texas Air One in a separate summary judgment motion. Docket No. 96 at 6 (arguing, as they did "in their earlier cross-motion[,]" that East Texas Air One "suffer[s] no injury" and "like other Plaintiffs . . . has not demonstrated . . . injury in fact")). Accordingly, the Court's discussion of standing applies to all Plaintiffs, including East Texas Air One.

"accept as valid the merits of [the plaintiffs'] legal claims." *FEC v. Ted Cruz for Senate*, 142 S. Ct. 1638, 1647 (2022) (citing *Warth v. Seldin*, 422 U.S. 490, 500 (1975)).

Here, Plaintiffs have established at least two injuries fairly traceable to the Final Rule. *First*, Plaintiffs assert that they have suffered a procedural injury because the Rule "deprive[s] them of the arbitration process established by the Act" and "replace[s] it with a different process that unlawfully 'puts a substantial thumb on the scale in favor of the QPA.'" Docket No. 82 at 3 (cleaned up) (quoting *TMA*, 587 F. Supp. 3d at 537). The process established by the Rule, Plaintiffs argue, makes it "more difficult for [a provider's] bid to be chosen, in comparison with a process in which [arbitrators] can freely consider all statutory factors without favoring any particular factor." Docket No. 41, Ex. A ¶¶ 15–16; *see also id.*, Ex. B ¶ 16 (same); *id.*, Ex. C ¶ 15 (same); *id.*, Ex. D ¶ 10 (same); Docket No. 64, Ex. 2 ¶ 4 (same); *TMA*, 587 F. Supp. 3d at 537; *LifeNet, Inc.*, 2022 WL 2959715, at *7.

This claimed procedural injury is sufficient to confer Article III standing. *TMA*, 587 F. Supp. 3d at 537 (citing *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) ("A plaintiff can show a cognizable injury if [he] has been deprived of a 'procedural right to protect [his] concrete interests.'") (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009)); *see also Lujan v. Defs. of Wildlife*, 504 U.S. 555, 573 n.8 (1992). The Departments argue that the Final Rule no longer includes a "presumption in favor of the [QPA]" and that no arbitrator would interpret the Rule in a way that harms providers. Docket No. 62 at 17–19. But Plaintiffs have presented evidence that the Rule *will* harm providers, *see infra* at 17–18, and in any event, need not

prove that following the proper procedure will necessarily create different outcomes. Plaintiffs must merely show a "reasonable claim of minimal impact" in failing to adhere to proper procedure, which they have done here. *Kinetica Partners, LLC v. U.S. Dep't of the Interior*, 505 F. Supp. 3d 653, 671 (S.D. Tex. 2020), *appeal dismissed*, 2021 WL 3377978 (5th Cir. Mar. 22, 2021) ("A procedural injury can suffice for standing even where the plaintiff does not prove that adherence to the proper procedure would have produced a different outcome because the likelihood and extent of impact are properly addressed in connection with the merits in a harmless error analysis."); *United States v. Johnson*, 632 F.3d 912, 921 n.45 (5th Cir. 2011); *see also TMA*, 587 F. Supp. 3d at 537; *LifeNet, Inc.*, 2022 WL 2959715, at *7.

Second, Plaintiffs have established that they will likely suffer financial harm because the Final Rule creates an arbitration process that will cause "the systematic reduction of out-of-network reimbursements." Docket No. 41, Ex. A ¶ 16; *id.*, Ex. B ¶ 16; *id.*, Ex. C ¶ 17 ("[R]equiring IDR entities to privilege the QPA will lower reimbursement rates for my services, such that my compensation will decrease."); Docket No. 42, Ex. G ¶¶ 15–17; Docket No. 64, Ex. 2 ¶ 4. Plaintiffs attest that they will "nearly always" submit offers that are higher and farther from the QPA than the offers submitted by the insurers. Docket No. 82 at 4; Docket No. 42, Ex. C ¶ 11; Docket No. 41, Ex. B ¶ 12; Docket No. 64, Ex. 2 ¶ 4. This is because the QPA does not "accurately reflect [the providers'] cost of providing services in most cases." *TMA*, 587 F. Supp. 3d at 538; Docket No. 41, Ex. A ¶ 13; *id.*, Ex. B ¶¶ 12–13; *id.*,

Ex. C ¶¶ 8–10; *id.*, Ex. D ¶8; Docket No. 64, Ex. 2 ¶ 4.[9] The Final Rule's QPA-centric approach will therefore injure Plaintiffs by causing arbitrators to select insurers' offers more often than they would under the process established by the Act. Docket No. 41, Ex. A ¶ 16; *id.*, Ex. B ¶ 16; *id.*, Ex. C ¶ 16; *id.*, Ex. D ¶ 10; Docket No. 42, Ex. G ¶15; Docket No. 64, Ex. 2 ¶ 4. Such "economic injury is a quintessential injury upon which to base standing." *El Paso Cnty. v. Trump*, 982 F.3d 332, 338 (5th Cir. 2020 (quoting *Tex. Democratic Party v. Benkiser*, 459 F.3d 582, 586 (5th Cir. 2006)).

The Departments argue that the Final Rule "does not actually do what Plaintiffs claim it does" and thus Plaintiffs cannot show they are likely to suffer an injury. Docket No. 62 at 18. But this argument "goes to the merits rather than standing." *Glen v. Am. Airlines, Inc.*, 7 F.4th 331, 335 (5th Cir. 2021). In determining standing, a court must accept the merits of the plaintiff's claims. *Ted Cruz for Senate*, 142 S. Ct. at 1647. And here, Plaintiffs claim that the Rule violates the Act by limiting arbitrators' discretion and privileging the QPA in the payment dispute process. Plaintiffs then submit detailed affidavits with specific facts establishing that the injuries arising from their claims are not only likely and imminent, but inevitable. *See, e.g.*, Docket No. 41, Ex. A ¶ 16; *id.*, Ex. B ¶ 16; *id.*, Ex. C ¶ 17; Docket No. 42,

[9] *See also* Brief of American Society of Anesthesiologists, *et al.*, as Amici Curiae in Support of Plaintiffs' Motions for Summary Judgment, Docket No. 53 at 8 (The QPA does "not accurately represent the fair market-based payment rates for out-of-network services."); Brief of American Medical Ass'n and American Hospital Ass'n as Amici Curiae in Support of Plaintiffs' Motions for Summary Judgment, Docket No. 54 at 17 (arguing the QPA does not reflect actual market rates); Brief of Emergency Department Practice Management Ass'n as Amicus Curiae in Support of Plaintiffs' Motion for Summary Judgment, Docket No. 55 at 7 (noting there is no basis for belief that the QPA will "typically" be a reasonable out-of-network rate).

Ex. G ¶¶ 15–17; Docket No. 64, Ex. 2 ¶ 4; *see also TMA*, 587 F. Supp. 3d at 538 (citing *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1118 (D.C. Cir. 2005) (finding "a sufficiently distinct and palpable injury" from agency action that had "immediate, unavoidable implications for [the plaintiff's] business choices"); *Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008) ("[S]tanding is usually self-evident when the plaintiff is a regulated party or an organization representing regulated parties.").

The Departments' reliance on *Missouri v. Yellen*, 39 F.4th 1063 (8th Cir. 2022), is misplaced. In that case, Missouri sued to enjoin an agency from adopting one of two potential interpretations of a rule before the agency published any guidance on how it would interpret the rule. *Id.* at 1069. The Eighth Circuit held that Missouri lacked standing because it was "not challenging the [regulation] as written, but rather a specific potential interpretation of the provision . . . ." *Id.* The Departments argue that Plaintiffs are making the same mistake here—attacking an unlikely interpretation of the Final Rule rather than the Rule itself. Docket No. 63 at 19. But unlike Missouri, Plaintiffs here are challenging the Final Rule as written—a Rule Plaintiffs contend unlawfully restricts arbitrators' discretion and improperly privileges the QPA over other statutory factors.[10]

[10] LifeNet and East Texas Air One also argue that they are "objects" of the Final Rule. Thus, there is "little question that the [agency] action or inaction has caused [them] injury." Docket No. 83 at 11; Docket No. 97 at 5 (incorporating LifeNet's standing arguments by reference); *see also Contender Farms, L.L.P. v. U.S. Dep't of Agric.*, 779 F.3d 258, 264 (5th Cir. 2015); *LifeNet, Inc.*, 2022 WL 295715, at *6. The Court agrees. As the Court previously held, "LifeNet is an object of the [interim] Rule because it is a 'nonparticipating provider' whose air ambulance services are subject to the Rule." *LifeNet, Inc.*, 2022 WL 295715, at *6. Indeed, the Court explained, "LifeNet's services will be analyzed and valued in the IDR process pursuant to the [interim] Rule," and it is LifeNet "whose

B.

The Departments also argue that Plaintiff LifeNet cannot show injury because "LifeNet is paid for its services by Air Methods Corporation . . . a fixed amount regardless of the amount Air Methods is reimbursed by an insurer or plan." Docket No. 62 at 21.

But, for the reasons provided in *LifeNet, Inc.*, 2022 WL 2959715, at *7–8, the Court finds that LifeNet has shown a significant risk of losing its contract with Air Methods—and thus all related profits—because of the Final Rule. Docket No. 42, Ex. 3 ¶ 13. The contract permits Air Methods to terminate the agreement if a "financially unviable" situation occurs. Docket No. 44 § 2.3. And when the Rule drives down reimbursement rates for air ambulance services, such an "unviable" situation is likely to occur. Docket No. 42, Ex. 3 ¶ 12; *see also LifeNet, Inc.*, 2022 WL 2959715, at *7. The Court held in *LifeNet, Inc.*: "An unviable situation, moreover, would almost certainly result in LifeNet's having to renegotiate its contract for a lower payment amount—or losing the contract altogether." *Id.* at *7. Although the Departments "recognize that this Court previously rejected their argument that LifeNet lack[s] standing," the Departments offer nothing to call the Court's holding into question. Docket No. 62 at 20.

* * *

Accordingly, for the reasons stated above, Plaintiffs have established Article III standing.

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training, experience, and quality and outcome measurements are to be considered by the arbitrator." *Id.* at *7. The same is true under the Final Rule for both LifeNet and East Texas Air One.

III.

Plaintiffs argue that the challenged provisions of the Final Rule exceed the Departments' statutory authority and conflict with the Act. Docket No. 41 at 15. They ask the Court to set aside these provisions under the APA. The Departments counter that the statute requires them to establish the IDR process by regulation and that they are entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Docket No. 63 at 22.

The APA requires a reviewing court to "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Court reviews an agency's statutory interpretation under the two-step *Chevron* framework. *See generally Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1014 (5th Cir. 2019) (discussing *Chevron*); *see also City of Arlington v. FCC*, 569 U.S. 290, 306–07 (2013). The first step determines "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 843. However, if the statute is ambiguous, the Court proceeds to step two: "asking whether the agency's construction is 'permissible.'" *Sw. Elec. Power Co.*, 920 F.3d at 1014 (quoting *Chevron*, 467 U.S. at 843).

As explained below, the Court concludes that the challenged provisions of the Final Rule conflict with the unambiguous statutory text and must be set aside.

A.

In determining whether Congress has unambiguously spoken through a statute, the Court applies all the "traditional tools of construction," including "text, structure, history, and purpose." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (quoting *Chevron*, 467 U.S. at 843 n.9; *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 707 (1991) (Scalia, J., dissenting)); *Gulf Fishermens Ass'n v. Nat'l Marine Fisheries Serv.*, 968 F.3d 454, 460 (5th Cir. 2020). "[W]here a statute's text is clear, courts should not resort to legislative history" and "should not introduce ambiguity through the use of legislative history." *Adkins v. Silverman*, 899 F.3d 395, 403 (5th Cir. 2018) (citing *BedRoc Ltd. v. United States*, 541 U.S. 176, 183 (2004) (plurality opinion)).

As the Court previously held, the Act is unambiguous. *See TMA*, 587 F. Supp. 3d at 541. The Act provides that arbitrators deciding which offer to select "shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii)." 42 U.S.C. § 300gg-111(c)(5)(C)(i). Clause (ii) lists five "circumstances" the arbitrator "shall" consider, including (1) "the level of training, experience, and quality and outcomes measurements of the provider or facility"; (2) the "market share held by the nonparticipating provider or facility"; (3) the "acuity of the individual receiving such item or service"; (4) the "teaching status, case mix, and scope of services of the nonparticipating facility"; and (5) "[d]emonstrations of good faith efforts (or lack of good faith efforts)" made by the provider and insurer to enter into a network agreement. § 300gg-111(c)(5)(C)(ii). Arbitrators must also consider any relevant information submitted by either party. § 300gg-111(c)(5)(B). Because "the word 'shall' usually connotes a requirement," the

Act plainly requires arbitrators to consider all the specified information in determining which offer to select. *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016).

Nothing in the Act, moreover, instructs arbitrators to weigh any one factor or circumstance more heavily than the others. *TMA*, 587 F. Supp. 3d at 541. A statute's "lack of text" is sometimes "more telling" than the text itself. *Gulf Fishermens Ass'n*, 968 F.3d at 460. And here, the Act nowhere states that the QPA is the primary or most important factor—or that it must be weighed more heavily than, or considered before, other factors. *See Am. Corn Growers Ass'n v. EPA*, 291 F.3d 1, 6 (D.C. Cir. 2002) (holding that where "no weights were assigned" to statutory factors, "treat[ing] one of the five statutory factors in such a dramatically different fashion distorts the judgment Congress directed"). Nor does the Act limit arbitrators' discretion in considering the statutory factors, impose heightened scrutiny on information related to the non-QPA factors, or create procedural hurdles before considering that information. Rather, the Act instructs arbitrators to select one of the two offers submitted by the parties after "taking into account the considerations specified in subparagraph (C)." 42 U.S.C. § 300gg-11(c)(5)(A)(i).

Because Congress spoke clearly on the issue relevant here, the Departments' interpretation of the statute is owed no *Chevron* deference. *See Chevron*, 467 U.S. at 843; *Gulf Fishermens Ass'n*, 968 F.3d at 459 ("[C]ourts will not defer to agency interpretation of an unambiguous statute.").

B.

It is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp.*, 573 U.S. at 328. But here, the Departments impermissibly altered the Act's requirements.

Rather than instructing arbitrators to consider all the factors pursuant to the Act, the Final Rule requires arbitrators to consider the QPA first and then restricts how they may consider information relating to the non-QPA factors. 45 C.F.R. § 149.510(c)(4)(iii). The Rule prohibits arbitrators from "giv[ing] weight" to such information unless several requirements are met: the information is "credible," "relates to the offer submitted by either party," and is not "already accounted for by the [QPA]." § 149.510(c)(4)(iii)(E). If an arbitrator "relies on" any of the non-QPA information, moreover, the arbitrator must explain in writing "why [the arbitrator] concluded that this information was not already reflected in the [QPA]." § 149.510(c)(4)(vi)(B). While avoiding an explicit presumption in favor of the QPA, the Final Rule nevertheless continues to place a thumb on the scale for the QPA by requiring arbitrators to begin with the QPA and then imposing restrictions on the non-QPA factors that appear nowhere in the statute. *See TMA*, 587 F. Supp. 3d at 542.

The Final Rule also improperly limits arbitrators' discretion by dictating how they may consider the statutory factors—in direct conflict with the Act. 42 U.S.C. § 300gg-111(c)(2)–(9). The Act includes detailed rules about who may serve as arbitrators, requiring them to have medical and legal expertise and certifying them

for five-year terms. § 300gg-111(c)(4). The Act then directs arbitrators to "select one of the offers submitted" after "taking into account" the statutory factors. § 300gg-111(c)(5)(A)(i). The Act thus vests discretion in the arbitrators—not the Departments—to determine the proper payment amount based on their expertise as set forth in the statute. *See, e.g.*, *New York v. Reilly*, 969 F.2d 1147, 1150 (D.C. Cir. 1992) ("Because Congress did not assign the specific weight the Administrator should accord each of these factors, the Administrator is free to exercise his discretion in this area."). Yet, the Final Rule attempts to control how arbitrators evaluate the information properly before them and "introduce[es] limitations not found in the statute." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020) ("Congress could have limited [the agency's] discretion in any number of ways, but it chose not to do so . . . . By introducing a limitation not found in the statute, respondents ask us to alter, rather than to interpret, the [statute]."); *see also TMA*, 587 F. Supp. 3d at 542.

The Departments argue that the Final Rule merely imposes "reasonable evidentiary and procedural rules" on the IDR process. Docket No. 62 at 26. But the Act already tells arbitrators what evidence they "shall consider" and what evidence they "shall not consider." § 300gg-111(c)(5)(C)–(D). And the Rule does more than the Departments admit. The Rule precludes arbitrators from "giv[ing] weight" to some information that the Act requires them to consider—*e.g.*, information relating to the non-QPA factors that happens to be "already accounted for" in the QPA. § 149.510(c)(4)(iii)(E). And the Rule attempts to dictate how arbitrators assess other

information—invading the adjudicative role assigned by the statute to the arbitrators, not the Departments. The authorities cited by the Departments, moreover, are inapposite because those cases involved agency-conducted adjudications—not independent arbitrations like those at issue here. *E.g.*, Docket No. 62 at 23 (citing, *e.g.*, *Nat'l Mining Ass'n v. Dep't of Labor*, 292 F.3d 849, 868 (D.C. Cir. 2002) (per curiam) ("We give particular deference to an agency's promulgation of evidentiary rules governing *its own adjudications*." (emphasis added))).

The Departments also argue the Final Rule simply fills a "gap" in the statute "concerning how to evaluate the various pieces of information that go into selecting payment amounts." Docket No. 62 at 27. But there is no "gap." The Act specifies in meticulous detail the qualifications for arbitrators and the information for them to consider. *E.g.*, 45 CFR § 149.510(e)(2) (explaining the requirements for certified IDR entities, including arbitration, claims administration, managed care, billing and coding, medical, and legal expertise as well as a current recognized accreditation). And when a statute lists factors for a decisionmaker to consider, the weighing of those factors is left to the decisionmaker's sound discretion. *See, e.g.*, *Ramirez v. ICE*, 471 F. Supp. 3d 88, 176 (D.D.C. 2020) ("[I]f 'Congress did not mandate any particular structure or weight' for an agency's consideration of a variety of factors, then the agency is left with 'discretion to decide how to account for the [factors Congress included in the statute], and how much weight to give each factor.'" (quoting *Weyerhaeuser Co. v. Costle*, 590 F.2d 1011 (D.C. Cir. 1978))). Although the Act authorizes the Departments to promulgate a rule establishing the IDR process, 42

U.S.C. § 300gg-111(c)(2)(A), the Departments may not promulgate a rule that conflicts with the Act or attempts to fill nonexistent statutory "gaps." *See Texas v. United States*, 809 F.3d 134, 186 (5th Cir. 2015) ("Were courts to *presume* a delegation of power absent an express *withholding* of such power, agencies would enjoy virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well." (quoting *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995))). *See generally* 45 C.F.R. § 149.510.

Further, the record in this case demonstrates that privileging the QPA remains the Department's intent behind the Final Rule. In implementing the interim final rule, the Departments expressly stated that the "rebuttable presumption for the appropriate payment amount" should be the QPA because that "will protect participants, beneficiaries, and enrollees from excessive costs, either through reduced costs for items and services or through decreased premiums." 86 Fed. Reg. 55,980 at 56,061. The Departments thus drafted the interim rule—in conflict with the statute—to ensure arbitrators would systematically choose the payment amount closest to the QPA. *See TMA*, 587 F. Supp. 3d at 542–43. Indeed, in *TMA*, the Departments argued that vacating the interim rule would result in higher reimbursement payments to providers, "would be highly disruptive" to insurance companies, and would "upend[] . . . efforts to control upward pressure on health care costs." *TMA*, No. 6:21-cv-425 (E.D. Tex. Feb. 2, 2022), ECF No. 104 at 17; *see also* Docket No. 63 at 10–11, 28.

The Departments' goal has not changed: "The goal of the [Final] [R]ule is to keep costs down." Docket No. 94 at 32:22–23. Although the Departments have abandoned the "rebuttable presumption" term, they have not relinquished their goal of privileging the QPA, tilting arbitrations in favor of insurers, and thereby lowering payments to providers.

Accordingly, for the reasons stated above, the challenged provisions of the Final Rule conflict with the Act and must be set aside under the APA.[11]

IV.

Having determined that the Final Rule violates the APA, the Court considers the proper remedy.

Plaintiffs ask the Court to vacate certain portions of the Rule. Docket No. 1 at 26; Docket No. 64 at 34. As before, Plaintiffs argue that the Final Rule is seriously deficient and cannot be rehabilitated because it conflicts with the unambiguous terms of the Act. Docket No. 41 at 29 (citing *TMA*, 587 F. Supp. 3d. at 548). Plaintiffs also argue that vacatur is especially warranted here, where the Departments "knew about many of the potential problems with the Final Rule" and "ignored or failed to adequately address them." *Id.* at 29–30 (citing *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021), *rev'd and remanded on other grounds*, 142 S. Ct. 2528 (2022) (noting

[11] Plaintiffs also argue that the challenged provisions of the Final Rule should be set aside as arbitrary and capricious. *See* Docket No. 41 at 26; Docket No. 42 at 9. Because the Court finds that the Final Rule conflicts with the Act and sets it aside under the APA on that basis, the Court need not address Plaintiffs' alternative argument. *See Flight Training Int'l, Inc. v. Fed. Aviation Admin.*, 58 F.4th 234 (5th Cir. 2023) ("In light of this disposition, we do not reach FTI's alternative argument that the Rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."); *Marable v. Dep't of Com.*, 857 F. App'x 836, 837 (5th Cir. 2021) ("Because we conclude that the first basis relied upon by the district court for summary judgment . . . is dispositive, we need not address" other grounds.).

that vacatur is appropriate where an agency is "on notice about the problems with its decision . . . and it still failed to correct them" (cleaned up)).

The Departments request that any relief be limited to the Plaintiffs in this case. Docket No. 63 at 41. According to the Departments, "[n]othing in the APA's directive to 'set aside' unlawful 'agency action' mandates that 'agency action' shall be set aside globally, rather than as applied to the plaintiffs." *Id.* (quoting 5 U.S.C. § 706(2)).

As the Court held in *TMA*, "by default, remand with vacatur is the appropriate remedy" when agency action is successfully challenged under the APA. 587 F. Supp. 3d at 548 (quoting *Texas v. Biden*, 20 F.4th at 1000); *see also Cargill v. Garland*, 56 F.4th 447, 472 (5th Cir. 2023) (en banc) ("[V]acatur of an agency action is the default rule in this Circuit."); *R.J. Reynolds Tobacco Co. v. U.S. FDA*, 2022 WL 17489170, at *21 (E.D. Tex. Dec. 7, 2022) (noting that the Fifth Circuit has interpreted "set aside" in the APA as "the remedy of vacatur").[12] And "the ordinary result" of setting aside unlawful rules is that "the rules are vacated—not that their application to the individual petitioners is proscribed." *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 944–45 (N.D. Tex. 2019) (quoting *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)); *TMA*, 587 F. Supp. 3d at 549.

[12] *See also, e.g.*, *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (holding that § 706's instruction for courts to "set aside" unlawful agency action means to vacate that action as to all parties); *Set Aside*, BLACK'S LAW DICTIONARY (3d ed. 1944) ("To set aside a judgment, decree, award, or any proceedings is to cancel, annul, or revoke them at the instance of a party unjustly or irregularly affected by them."). *But see Arizona v. Biden*, 40 F.4th 375, 395 (6th Cir. 2022) (Sutton, C.J., concurring) (explaining that § 706's "set aside . . . ." does not support disregarding "the long-understood view of equity—that courts issue judgments that bind the parties in each case over whom they have personal jurisdiction").

Further, the same factors the Court considered in *TMA*—the "seriousness of the deficiencies of the action" and "the disruptive consequences of vacatur"—again weigh in favor of vacatur here. *TMA*, 2022 WL 542879, at *14 (citing *Texas v. Biden*, 20 F.4th at 1000). *First*, the Final Rule "conflicts with the unambiguous terms of the Act," meaning that the Departments cannot justify the challenged portions of the Rule on remand. *Id.* (citing *Sw. Elec. Power Co.*, 920 F.3d at 1022 (vacating and remanding part of final rule that was contrary to statute)). *Second*, "vacatur will not be unduly disruptive" as the "remaining provisions of the Rule and the Act itself provide a sufficient framework" for all interested parties to resolve payment disputes. *Id.*

The Departments provide only one reason to reconsider these factors. They argue that vacatur "would be highly disruptive, as it would leave arbitrators with no guidance as to how to proceed with their decision-making." Docket No. 62 at 42. But the "only consequence of vacatur will be that arbitrators will decide cases under the statute as written without having their hands tied by the Departments." *TMA*, 587 F. Supp. 3d at 549. And here, vacatur would preserve the status quo because arbitrators have been—and are presently—deciding payment disputes pursuant to the statute since the Court vacated the interim final rule nearly a year ago.

Accordingly, the proper remedy is vacatur of the challenged provisions and remand to the Departments for "further consideration in light of this opinion."[13] *Franciscan All., Inc.*, 414 F. Supp. 3d at 945.

[13] Plaintiffs also ask the Court to "remand to the Departments with specific instructions" on how to

V.

In sum, the Court holds that (1) Plaintiffs have standing to challenge the Final Rule, (2) the Rule conflicts with the unambiguous terms of the Act, and (3) vacatur and remand of the challenged portions of the Rule is the proper remedy.

Accordingly, the Court **GRANTS** Plaintiffs TMA, Dr. Adam Corley, and Tyler Regional Hospital's motion for summary judgment (Docket No. 41), **GRANTS** Plaintiffs LifeNet and East Texas Air One's motion for summary judgment (Docket No. 42), **DENIES** Defendants' cross-motions for summary judgment (Docket Nos. 63, 96), and **ORDERS** that the following provisions of the Final Rule are **VACATED** and **REMANDED** for further consideration in light of this Opinion:

(1) The word "then" in 45 C.F.R. § 149.510(c)(4)(iii)(B); the entirety of 45 C.F.R. §§ 149.510(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 45 C.F.R. § 149.510(c)(4)(vi)(B);

(2) The word "then" in 26 C.F.R. § 54.9816-8(c)(4)(iii)(B); the entirety of 26 C.F.R. § 54.9816-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 26 C.F.R. § 54.9816-8(c)(4)(vi)(B);

(3) The word "then" in 29 C.F.R. § 2590-716-8(c)(4)(iii)(B); the entirety of 29 C.F.R. § 2590-716-8(c)(4)(iii)(E) and (c)(4)(iv); and the final sentence of 29 C.F.R. § 2590-716-8(c)(4)(vi)(B);

(4) The entirety of 45 C.F.R. § 149.520(b)(3);

(5) The entirety of 26 C.F.R. § 54.9817-2(b)(3); and

(6) The entirety of 29 C.F.R. § 2590-717-2(b)(3).

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implement any future rule. Docket No. 41 at 30. Plaintiffs acknowledge this is appropriate only "in exceptional cases," but argue that the Departments "failed to comply with a previous court order" or otherwise "repeatedly failed to respect the governing law." *Id.* (citing *Sierra Club. v. EPA*, 346 F.3d 955, 963 (9th Cir. 2003); *Fiber Glass Sys., Inc. v. NLRB*, 807 F.2d 461, 463 (5th Cir. 1987); *Earth Island Inst. v. Hogarth*, 494 F.3d 757, 769–70 (9th Cir. 2007)). The Court disagrees. Although mistaken, the Departments attempted to draft a rule in accord with the statute and the Court's prior order. 87 Fed. Reg. at 52,624–25 (detailing this Court's rulings and discussing changes made in response). This is therefore not an "exceptional case" warranting the requested remand. *Cf., e.g.*, *Fiber Glass Sys.*, 807 F.2d at 463 (remanding with instructions only after "repeatedly direct[ing]" the agency, on at least seven cited occasions, to comply with circuit precedent).

So **ORDERED** and **SIGNED** this **6th** day of **February, 2023.**

JEREMY D. KERNODLE
UNITED STATES DISTRICT JUDGE

TAB 8

(*Requirements Related to Surprise Billing*)

52618 Federal Register / Vol. 87, No. 165 / Friday, August 26, 2022 / Rules and Regulations

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9965]

RIN 1545–BQ01 and 1545–BQ02

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB99 and 1210–AC00

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 149

[CMS–9909–F and CMS–9908–F]

RIN 0938–AU62 and RIN 0938–AU63

Requirements Related to Surprise Billing

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document includes final rules under the No Surprises Act, which was enacted as part of the Consolidated Appropriations Act, 2021 (CAA). The document finalizes certain disclosure requirements relating to information that group health plans, and health insurance issuers offering group or individual health insurance coverage, must share about the qualifying payment amount (QPA) under the interim final rules issued in July 2021, titled *Requirements Related to Surprise Billing; Part I* (July 2021 interim final rules). Additionally, this document finalizes select provisions under the October 2021 interim final rules, titled *Requirements Related to Surprise Billing; Part II* (October 2021 interim final rules), to address certain requirements related to consideration of information when a certified independent dispute resolution (IDR) entity makes a payment determination under the Federal IDR process.

DATES: *Effective date:* These final rules are effective on October 25, 2022.

Applicability date: See Section III of the **SUPPLEMENTARY INFORMATION** section for information on the applicability dates.

FOR FURTHER INFORMATION CONTACT: Shira McKinlay, Internal Revenue Service, Department of the Treasury, at 202–317–5500; Elizabeth Schumacher or David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202–693–8335; Deborah Bryant, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301–492–4293; Lindsey Murtagh, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 301–492–4106.

Customer Service Information

Individuals interested in obtaining information from the Department of Labor (DOL) concerning employment-based health coverage laws may call the Employee Benefits Security Administration (EBSA) Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the DOL's website (*www.dol.gov/agencies/ebsa*).

In addition, information from the Department of Health and Human Services (HHS) on private health insurance coverage, coverage provided by non-Federal governmental group health plans, and requirements that apply to health care providers, health care facilities, and providers of air ambulance services can be found on the Centers for Medicare & Medicaid Services (CMS) website (*www.cms.gov/cciio*), and information on surprise medical bills can be found at *www.cms.gov/nosurprises*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Preventing Surprise Medical Bills Under the CAA

On December 27, 2020, the CAA, which includes the No Surprises Act, was enacted.[1] The No Surprises Act provides Federal protections against surprise billing by limiting out-of-network cost sharing and prohibiting "balance billing," in many of the circumstances in which surprise bills arise most frequently. Balance billing refers to the practice of out-of-network providers billing patients for the difference between: (1) the provider's billed charges, and (2) the amount collected from the plan or issuer plus the amount collected from the patient in the form of cost sharing (such as a copayment, coinsurance, or amounts paid toward a deductible). In particular, the No Surprises Act added new provisions applicable to group health plans and health insurance issuers offering group or individual health insurance coverage to Subchapter B of chapter 100 of the Internal Revenue Code (Code), Part 7 of the Employee Retirement Income Security Act (ERISA), and Part D of title XXVII of the Public Health Service Act (PHS Act). Section 102 of the No Surprises Act added section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act,[2] which contain limitations on cost sharing and requirements regarding the timing of initial payments and notices of denial of payment for emergency services furnished by nonparticipating providers and emergency facilities, and for non-emergency services furnished by nonparticipating providers with respect to patient visits to participating health care facilities, defined as hospitals, hospital outpatient departments, critical access hospitals, and ambulatory surgical centers. Section 103 of the No Surprises Act amended section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act to establish a Federal IDR process that allows plans and issuers and nonparticipating providers and facilities to resolve disputes regarding out-of-network rates. Section 105 of the No Surprises Act added section 9817 of the Code, section 717 of ERISA, and section 2799A–2 of the PHS Act. These sections contain limitations on cost sharing and requirements for the timing of initial payments and notices of denial of payment for air ambulance services furnished by nonparticipating providers of air ambulance services, and allow plans and issuers and nonparticipating providers of air ambulance services to access the Federal IDR process described in section 9816 of the Code, section 716 of ERISA, and section 2799A–1 of the PHS Act.

The No Surprises Act provisions that apply to health care providers, facilities, and providers of air ambulance services, such as prohibitions on balance billing for certain items and services and requirements related to disclosures about balance billing protections, were added to title XXVII of the PHS Act in a new part E.

The Departments of the Treasury, Labor, and Health and Human Services

[1] Public Law 116–260 (December 27, 2020).

[2] Section 102(d)(1) of the No Surprises Act amended the Federal Employees Health Benefits Act, 5 U.S.C. 8901 *et seq.*, by adding a new subsection (p) to 5 U.S.C. 8902. Under this new provision, each Federal Employees Health Benefits (FEHB) Program contract must require a carrier to comply with requirements described in sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A–1 and 2799A–2 of the PHS Act (as applicable) in the same manner as these provisions apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

(the Departments) previously issued interim final rules implementing provisions of sections 9816 and 9817 of the Code, sections 716 and 717 of ERISA, and sections 2799A–1 and 2799A–2 of the PHS Act to protect consumers from surprise medical bills for emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services.[3] The interim final rules also implement provisions requiring the Departments to create a Federal IDR process to determine payment amounts when there is a dispute between payers and providers or facilities over the out-of-network rate due for emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to participating facilities in certain circumstances, and air ambulance services furnished by nonparticipating providers of air ambulance services.[4] To implement these provisions, the Departments published in the **Federal Register** the July 2021 interim final rules on July 13, 2021 (86 FR 36872), and the October 2021 interim final rules on October 7, 2021 (86 FR 55980).[5] The July 2021 interim final rules and October 2021 interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; and to health care providers and facilities, and providers of air ambulance services with respect to items and services provided during plan years (in the individual market, policy years) beginning on or after January 1, 2022.[6]

[3] 86 FR 36872 (July 13, 2021) and 86 FR 55980 (October 7, 2021).

[4] The Federal IDR process does not apply if an All-Payer Model Agreement under section 1115A of the Social Security Act or a specified State law applies.

[5] The interim final rules also include interim final regulations under 5 U.S.C. 8902(p) issued by the Office of Personnel Management that specify how certain provisions of the No Surprises Act apply to health benefit plans offered by carriers under the Federal Employees Health Benefits Act.

[6] 86 FR 36872 (July 13, 2021) and 86 FR 55980 (October 7, 2021). These provisions apply to carriers in the Federal Employees Health Benefits Program with respect to contract years beginning on or after January 1, 2022. The disclosure requirements at 45 CFR 149.430 regarding patient protections against balance billing are applicable as of January 1, 2022.

B. July 2021 Interim Final Rules

The July 2021 interim final rules implement sections 9816(a)–(b) and 9817(a) of the Code, sections 716(a)–(b) and 717(a) of ERISA, and sections 2799A–1(a)–(b), 2799A–2(a), 2799A–7, 2799B–1, 2799B–2, 2799B–3, and 2799B–5 of the PHS Act.

Among other requirements, the July 2021 interim final rules generally prohibit balance billing for items and services subject to the requirements in those interim final rules.[7] The July 2021 interim final rules also specify that consumer cost-sharing amounts for emergency services furnished by nonparticipating providers or facilities, and for non-emergency services furnished by nonparticipating providers with respect to patient visits to certain participating facilities, must be calculated based on the ''recognized amount,'' which is defined as one of the following amounts: (1) an amount determined by an applicable All-Payer Model Agreement under section 1115A of the Social Security Act; (2) if there is no such applicable All-Payer Model Agreement, an amount determined by a specified State law; or (3) if there is no such applicable All-Payer Model Agreement or specified State law, the lesser of the billed charge or the QPA. The July 2021 interim final rules establish the methodology for calculating the QPA, which in most circumstances will be the plan's or issuer's median contracted rate that was in effect for the particular item or service on January 31, 2019, increased for inflation. Cost-sharing amounts for air ambulance services provided by nonparticipating providers of air ambulance services must be the same as the cost-sharing amounts that would apply if the services were provided by a participating provider of air ambulance services, and these cost-sharing amounts must be calculated using the lesser of the billed charge or the QPA.

The No Surprises Act directs the Departments to specify the information that a plan or issuer must share with a nonparticipating provider, nonparticipating emergency facility, or nonparticipating provider of air ambulance services, as applicable, after determining the QPA. Therefore, 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d) require that plans and issuers make certain disclosures about the QPA with each initial payment or notice of denial of payment, and that plans and issuers provide certain additional information upon request of the provider, facility, or provider of air ambulance services. This information must be provided in writing, either on paper or electronically, to a nonparticipating provider, facility, or provider of air ambulance services, as applicable, when the QPA serves as the recognized amount.

[7] 45 CFR 149.410(a), 149.420(a), and 149.440(a).

With an initial payment or notice of denial of payment, a plan or issuer must provide the QPA for each item or service involved as well as a statement certifying that, based on the determination of the plan or issuer: (1) the QPA applies for purposes of the recognized amount (or, in the case of air ambulance services, for calculating the participant's, beneficiary's, or enrollee's cost sharing), and (2) each QPA shared with the provider, facility, or provider of air ambulance services was determined in compliance with the methodology outlined in the July 2021 interim final rules.

A plan or issuer is also required to provide a statement that, if the provider, facility, or provider of air ambulance services wishes to initiate a 30-day open negotiation period for purposes of determining the amount of total payment, the provider, facility, or provider of air ambulance services may contact the appropriate person or office to initiate open negotiation, and that if the 30-day open negotiation period does not result in an agreement on the payment amount, the provider, facility, or provider of air ambulance services typically may initiate the Federal IDR process within 4 days after the end of the open negotiation period. The Departments note that these time frames are measured in business days, and plans and issuers should reflect this in the statement. The plan or issuer must provide contact information, including a telephone number and email address, for the appropriate office or person for the provider, facility, or provider of air ambulance services to contact to initiate open negotiation for purposes of determining an amount of payment (with the amount including cost sharing) for the item or service.

It has come to the Departments' attention that some plans and issuers are requiring nonparticipating providers, nonparticipating emergency facilities, and nonparticipating providers of air ambulance services to utilize plan- or issuer-owned web systems to initiate an open negotiation period. As discussed earlier, the July 2021 interim final rules require plans and issuers to provide a telephone number and email address for providers, facilities, and providers of air ambulance services to initiate the open

negotiation period. When a party to a payment dispute chooses to initiate the open negotiation period, the October 2021 interim final rules specify that the party must use the standard notice of initiation of open negotiation issued by the Departments and may satisfy the requirement to provide notice to the opposing party by sending the notice electronically if the party sending the notice has a good faith belief that the electronic method is readily accessible to the other party and the notice is also provided free of charge in paper form upon request.[8] For example, it is reasonable for a provider, facility, or provider of air ambulance services to have a good faith belief that an email address provided by a plan or issuer with the initial payment or notice of denial of payment is readily accessible to the plan or issuer. Thus, if a provider, facility, or provider of air ambulance services sends the standard notice of initiation of open negotiation to the email address identified by the plan or issuer in the notice of denial of payment or initial payment, that transmission would satisfy the regulatory requirement to provide notice to the opposing party (so long as the provider, facility, or provider of air ambulance services also sends the notice free of charge in paper form upon request).[9] Although plans and issuers may encourage the use of an online portal for nonparticipating providers, facilities, and providers of air ambulance services to submit the information necessary to initiate the open negotiation period, or may seek additional information to inform good faith open negotiations, such as through use of a supplemental open negotiation form, the July 2021 interim final rules require plans and issuers to provide a telephone number and email address for providers, facilities, and providers of air ambulance services to initiate the open negotiation period, and the October 2021 interim final rules permit a party to initiate the open negotiation period by sending the standard notice of initiation electronically to the email address identified in the notice of denial of payment or initial payment. Accordingly, a plan or issuer cannot refuse to accept the standard notice of initiation of open negotiation from a provider, facility, or provider of air ambulance services because the provider or facility did not utilize the plan's or issuer's online portal when the standard notice of initiation of open negotiation is provided in a manner consistent with the requirements of the July 2021 and October 2021 interim final rules.

In addition, upon request by the provider, facility, or provider of air ambulance services, a plan or issuer must provide, in a timely manner, information about whether the QPA includes contracted rates that were not set on a fee-for-service basis for the specific items and services and whether the QPA for those items and services was determined using underlying fee schedule rates or a derived amount.[10] If an eligible database was used to determine the QPA, the plan or issuer must provide information to identify which database was used. Similarly, if a related service code was used to determine the QPA for an item or service billed under a new service code, the plan or issuer must provide information to identify which related service code was used.

Finally, upon request by the provider, facility, or provider of air ambulance services, the plan or issuer must provide a statement, if applicable, that the plan's or issuer's contracted rates include risk-sharing, bonus, penalty, or other incentive-based or retrospective payments or payment adjustments that were excluded for purposes of calculating the QPA for the items and services involved.

C. October 2021 Interim Final Rules

The October 2021 interim final rules build on the July 2021 interim final rules and implement the Federal IDR process under sections 9816(c) and 9817(b) of the Code, sections 716(c) and 717(b) of ERISA, and sections 2799A–1(c) and 2799A–2(b) of the PHS Act.

The October 2021 interim final rules provide for a Federal IDR process that group health plans and health insurance issuers offering group or individual health insurance coverage and nonparticipating providers, facilities, and providers of air ambulance services may use to determine the out-of-network rate for items and services that are emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to participating facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services, where an All-Payer Model Agreement or specified State law does not apply. The October 2021 interim final rules generally specify rules to implement the Federal IDR process, including the requirements governing the open negotiation period; the initiation of the Federal IDR process; the Federal IDR process following initiation, including the selection of a certified IDR entity, submission of offers, payment determinations, and written decisions; costs of the Federal IDR process; certification of IDR entities, including the denial or revocation of certification of an IDR entity; and the collection of information related to the Federal IDR process from certified IDR entities to satisfy reporting requirements under the statute.

The October 2021 interim final rules provide that, not later than 30 business days after selection of a certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer and the provider, facility, or provider of air ambulance services to be the out-of-network rate for the qualified IDR item or service.[11] For each qualified IDR item or service, the amount by which this out-of-network rate exceeds the cost-sharing amount for the qualified IDR item or service is the total plan or coverage payment (with any initial payment made by the plan or issuer counted towards the total plan or coverage payment).

The October 2021 interim final rules state that, in selecting the offer, the certified IDR entity must consider the QPA for the applicable year for the same or similar item or service, or, in the case of batched or bundled items or services, the QPA or QPAs for the applicable year. The preamble to the July 2021 interim final rules provides that if multiple items and services are reimbursed under non-fee-for-service contractual arrangements, such as a bundled or capitated arrangement, and are billed for under a single billing code, plans and issuers must calculate a QPA for each item or service using the underlying fee schedule rates for the relevant items and services if the underlying fee schedule rates are available.[12] If there is no underlying fee schedule rate for an item or service, the plan or issuer must calculate the QPA

[8] 26 CFR 54.9816–8T(b)(2)(iii)(B), 29 CFR 2590.716–8(b)(2)(iii)(B), and 45 CFR 149.510(b)(2)(iii)(B).

[9] 86 FR 55980, 55990 (Oct. 7, 2021).

[10] 26 CFR 54.9816–6T(d)(2)(i), 29 CFR 2590.716–6(d)(2)(i), and 45 CFR 149.140(d)(2)(i). Under the July 2021 interim final rules, plans and issuers are required to calculate the QPA using underlying fee schedule rates or derived amounts when the plan or issuer has sufficient information to calculate the median of its contracted rates, but the payments under the contractual agreements are not on a fee-for-service basis (such as bundled or capitation payments). 26 CFR 54.9816–6T(b)(2)(iii), 29 CFR 2590.716–6(b)(2)(iii), 45 CFR 149.140(b)(2)(iii). Plans and issuers are not otherwise permitted to use underlying fee schedule rates or derived amounts to calculate the QPA.

[11] Qualified IDR item or service has the same meaning as set forth in 26 CFR 54.9816–8T(a)(2)(xii), 29 CFR 2590.716–8(a)(2)(xii), and 45 CFR 149.510(a)(2)(xii).

[12] 86 FR 36893 (July 13, 2021).

using a derived amount.[13] In addition, the October 2021 interim final rules state that the certified IDR entity must also consider information requested by, or submitted by the parties to, the certified IDR entity relating to the offer, to the extent a party provides credible information that is not otherwise prohibited under 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v).

The October 2021 interim final rules also require the parties to provide certain information to the certified IDR entity, including practice size and practice specialty or type; geographic region used to calculate the QPA; the QPA for the applicable year for the same or similar item or service as the qualified IDR item or service; and, if applicable, information showing that the Federal IDR process is inapplicable to the dispute. In addition, prior to vacatur in the United States District Court for the Eastern District of Texas, in the cases of *Texas Medical Association, et al.* v. *United States Department of Health and Human Services, et al.,* Case No. 6:21–cv–425 (E.D. Tex.) (*Texas Medical Association*) (February 23, 2022) and *LifeNet, Inc.* v. *United States Department of Health and Human Services, et al.,* Case No. 6:22–cv–162 (E.D. Tex.) (*LifeNet*) (July 26, 2022), these interim final rules specified that the certified IDR entity may request additional information relating to the parties' offers and must consider credible additional information submitted, as further described in the next paragraph, that relates to the parties' offers and the qualified IDR item or service that is the subject of a payment determination to determine if the information submitted clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate (unless the information relates to a factor that the certified IDR entity is prohibited from considering). For this purpose, the October 2021 interim final rules specify that credible information is information that upon critical analysis is worthy of belief and is trustworthy.[14] Prior to vacatur in *Texas Medical Association,* the term ''material difference'' was defined to mean a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the information important in determining the out-of-network rate and view the information as showing that the QPA is not the appropriate out-of-network rate.[15]

For items and services that are not air ambulance services, in determining which offer to select, the certified IDR entity must consider the following additional information under certain circumstances:

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 who received 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 and the plan or issuer during the previous 4 plan years.

Under the October 2021 interim final rules, the certified IDR entity may only consider this information submitted by the parties if the information is credible and relates to the offer submitted by either party.[16] The certified IDR entity may not consider any information submitted on the prohibited factors, including usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges); the amount that would have been billed if the provider, facility, or provider of air ambulance services were not subject to a prohibition on balance billing; and payment or reimbursement rates payable by a public payor, in whole or in part, for items and services furnished by the providers, facilities, or providers of air ambulance services.[17]

The October 2021 interim final rules also provided, prior to vacatur in *Texas Medical Association* and *LifeNet,* that after considering the QPA, additional information requested by the certified IDR entity from the parties, and all of the credible information submitted by the parties that is consistent with the requirements and is not prohibited information, the certified IDR entity must select the offer closest to the QPA, unless the certified IDR entity determined that the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the QPA but in opposing directions. In those cases, the October 2021 interim final rules required the certified IDR entity to select the offer that the certified IDR entity determines best represents the value of the item or service, which could be either party's offer.

Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must notify parties to the dispute of the selection of the offer and provide a written decision,[18] which must be submitted to the parties and the Departments through the Federal IDR portal.[19] The October 2021 interim final rules also provided that if the certified IDR entity did not choose the offer closest to the QPA, this written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate.

The October 2021 interim final rules also implemented the Federal IDR process for qualified IDR services that are air ambulance services. The process for a certified IDR entity to select an offer in a dispute related to qualified IDR services that are air ambulance services is essentially the same as that for other qualified IDR items or services. As with disputes related to qualified IDR items or services that are not air

[13] The Departments also specify an alternative method to calculate the QPA when there is insufficient information based on contracted rates. *See* 26 CFR 54.9816–6T(c)(2)–(4), 29 CFR 2590.716–6(c)(2)–(4), and 45 CFR 149.140(c)(2)–(4).

[14] 26 CFR 54.9816–8T(a)(2)(v), 29 CFR 2590.716–8(a)(2)(v), and 45 CFR 149.510(a)(2)(v).

[15] 26 CFR 54.9816–8T(a)(2)(viii), 29 CFR 2590.716–8(a)(2)(viii), and 45 CFR 149.510(a)(2)(viii).

[16] This requirement was vacated by the District Court in *Texas Medical Association.*

[17] 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). For this purpose, payment or reimbursement rates payable by a public payor include payments or reimbursement rates under the Medicare program under title XVIII of the Social Security Act, the Medicaid program under title XIX of the Social Security Act, the Children's Health Insurance Program under title XXI of the Social Security Act, the TRICARE program under chapter 55 of title 10, United States Code, chapter 17 of title 38, United States Code, and payment rates for demonstration projects under section 1115 of the Social Security Act.

[18] 26 CFR 54.9816–8T(c)(4)(vi)(A), 29 CFR 2590.716–8(c)(4)(vi)(A), and 45 CFR 149.510(c)(4)(vi)(A).

[19] The Federal IDR portal is available at *https://www.nsa-idr cms.gov* and must be used throughout the Federal IDR process to maximize efficiency and reduce burden.

ambulance services, in determining which offer to select, the No Surprises Act and October 2021 interim final rules provide that the certified IDR entity must consider the QPA for the applicable year for the qualified IDR services that are air ambulance services. The No Surprises Act and the October 2021 interim final rules likewise specified additional circumstances, in addition to the QPA, that the certified IDR entity must consider in making the payment determination for air ambulance services. With respect to air ambulance services, the certified IDR entity is required to consider, to the extent the parties provide credible information, a different set of additional circumstances:

1. The quality and outcomes measurements of the provider that furnished the services.

2. The acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee.

3. The training, experience, and quality of the medical personnel that furnished the air ambulance services.

4. Ambulance vehicle type, including the clinical capability level of the vehicle.

5. Population density of the point of pick-up (as defined in 42 CFR 414.605) for the air ambulance (such as urban, suburban, rural, or frontier).

6. Demonstrations of good faith efforts (or lack thereof) made by the nonparticipating provider of air ambulance services or the plan or issuer to enter into network agreements with each other and, if applicable, contracted rates between the provider of air ambulance services and the plan or issuer during the previous 4 plan years.

As with qualified IDR items or services that are not air ambulance services, the October 2021 interim final rules provide that after considering the QPA, additional information requested by the certified IDR entity from the parties, and all of the credible information submitted by the parties that is consistent with the requirements and is not prohibited information, the certified IDR entity must select the offer closest to the QPA, unless the certified IDR entity determined that the credible information submitted by the parties clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the QPA but in opposing directions. In those cases, the October 2021 interim final rules require the certified IDR entity to select the offer that the certified IDR entity determined best represents the value of the item or service, which could be either party's offer.

D. Public Comments Received in Response to the July 2021 and October 2021 Interim Final Rules

In response to the July 2021 and October 2021 interim final rules, the Departments received thousands of comments on many different aspects of the rules. In particular, the Departments received many comments related to a clarification in the preamble to the October 2021 interim final rules [20] stating that the July 2021 interim final rules do not require the plan or issuer to calculate the participant's, beneficiary's, or enrollee's cost sharing using the QPA for the service code submitted by the provider or facility, and that instead the plan or issuer could calculate the participant's, beneficiary's, or enrollee's cost sharing using the QPA for a downcoded service code that the plan or issuer determined was more appropriate. Many of these comments addressed the information required by the July 2021 interim final rules that must be shared about the QPA, the importance of this disclosure, and how additional disclosures related to the QPA would be useful in the context of the Federal IDR process, particularly when the QPA is based on a service code or modifier that is different than the one the provider or facility billed. The Departments also received many comments related to the payment determination standards under the Federal IDR process, including the provisions that govern the certified IDR entity's consideration of the enumerated factors. These final rules address only the provisions related to these comments, and they make changes in light of the decisions in *Texas Medical Association* and *LifeNet.* The Departments intend to address comments related to other provisions of the July 2021 and October 2021 interim final rules, including comments received in response to the July 2021 interim final rules related to the disclosure requirements that are not specifically related to downcoded service codes, at a later date.

1. QPA Disclosure Requirements

With respect to the information that must be shared about the QPA, the Departments received comments on both the July 2021 interim final rules and the October 2021 interim final rules supporting the disclosure requirement and emphasizing the importance of ensuring that the QPA and other information related to the item or service are provided to providers, facilities, and providers of air ambulance services at the time of the initial payment or notice of denial of payment. Many commenters on the July 2021 interim final rules stressed that the methodology to calculate the QPA should be transparent, and that the Departments should expand the range of information that is shared with providers, facilities, and providers of air ambulance services with the QPA. Some commenters felt the degree of disclosure was insufficient, and that it provided too much power and discretion to plans and issuers. Others, however, questioned whether plans, in particular, would be able to obtain the information required under the July 2021 interim final rules, as much of the information may be in the control of vendors or other service providers. In particular, the Departments received comments in response to the July 2021 interim final rules and the October 2021 interim final rules requesting that the disclosures that must be provided with each initial payment or notice of denial of payment include additional information about how the QPA was determined to ensure that providers, facilities, and providers of air ambulance services have sufficient information when the Federal IDR process is used for a payment determination. For example, commenters requested that plans and issuers be required, without a request, to provide information on the number of contracts and the geographic region used to calculate the QPA, whether the QPA is based on downcoding [21] of the billed claim, information about the use of modifiers in calculating the QPA, the types of specialties and subspecialties that have contracted rates included in the data set used to determine the QPA, and whether bonuses and supplemental payments were paid to in-network providers.

The manner in which items and services are coded, including the concept of downcoding claims was reflected in both the July 2021 interim final rules and the October 2021 interim final rules. The preamble to the July 2021 interim final rules noted that it is important that the QPA methodology account for modifiers that affect payment rates.[22] The preamble to the

[20] See 86 FR 55997–98 n.35.

[21] Downcode is defined in these final rules at 26 CFR 54.9816–6, 29 CFR 2590.716–6, and 45 CFR 149.30, to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

[22] The preamble to the July 2021 interim final rules also noted that modifiers affect the payment

October 2021 interim final rules noted that the Departments are aware that some plans and issuers review claims and alter the service code or modifier submitted by the provider or facility to another service code or modifier that the plan or issuer determines to be more appropriate (a practice commonly referred to as ''downcoding'' when the adjustment results in a lower reimbursement, as noted in the preamble to the October 2021 interim final rules).[23] Some commenters expressed concern that plans and issuers may calculate the QPA for a lower level service code (and/or modifier) instead of calculating the QPA for the particular service code or modifier specified in the claim submitted for reimbursement. These commenters stated that it is important for providers and facilities to know whether the plan or issuer has downcoded a particular claim that is subject to the balance billing protections in the No Surprises Act to ensure that providers receive information that may be relevant to the open negotiation process and that could inform a provider's offer in the Federal IDR process, and which the provider has no other means of ascertaining. Several commenters requested that these final rules require plans and issuers to disclose whether the claim has been downcoded for purposes of computing the QPA and include an explanation of why the claim was downcoded, as well as what the QPA would have been had the claim not been downcoded.

2. Payment Determination Standards Under the Federal IDR Process

With respect to the payment determination standards under the Federal IDR process, the Departments received numerous comments from various stakeholders about the provisions that govern the certified IDR entity's consideration of the statutory factors during the payment determination process. Many commenters supported the approach set forth in the October 2021 interim final rules that directs the certified IDR entity to begin with the QPA as a baseline when making a payment determination, which those commenters highlighted as an important part of the payment determination process that would ensure that the surprise billing provisions lead to lower health care costs for all consumers. Furthermore, some commenters stated that the approach taken in the October 2021 interim final rules is crucial to achieving the budget savings the Congressional Budget Office calculated. Those commenters stated that the approach taken would shield consumers from surprise bills and ever higher insurance premium costs. Commenters stated that the October 2021 interim final rules reinforce the statutory directive that the QPA is the primary consideration for the certified IDR entity. Commenters also stated this use of the QPA represents a reasonable, market-based rate and would encourage greater participation in health plan networks.

Commenters noted that there may be circumstances in which the appropriate out-of-network rate would exceed the QPA, and that the October 2021 interim final rules properly provide a pathway for the certified IDR entity to reach that determination when it can be justified. These commenters highlighted that nothing in the October 2021 interim final rules required a certified IDR entity to default to the selection of the QPA or the offer closest to it, but rather that the rule correctly mandated that all credible information be considered. Commenters also stated that it was not unreasonable to require a party to document why the QPA is not the appropriate payment amount. Other commenters raised concerns about giving the same weight to all factors because many of the additional circumstances outlined in the rule, such as patient acuity and complexity of care, could already be incorporated into the QPA calculation. Commenters also noted that the October 2021 interim final rules provide clear guidance to certified IDR entities, which would reduce variability in payment determinations and better position the parties to settle disputes before reaching the Federal IDR process, by giving the parties a better sense of how payment determinations would be made.

Other commenters disagreed with the approach under the October 2021 interim final rules and expressed opposition to the emphasis placed on the QPA during the Federal IDR process. Many of these commenters criticized the rule as establishing a rebuttable presumption in favor of the QPA as the out-of-network rate while failing to equip the parties with the necessary information to rebut the presumption. Some commenters stated that the Departments disregarded bipartisan Congressional intent and tipped the scales in the Federal IDR process in favor of health plans and issuers. Commenters expressed concern that emphasizing the QPA ignores the complexity of billing factors, such as modifiers and the practice of bundling multiple health care services under a single billing code, and creates an incentive for the plan or issuer to downcode claims in bad faith. Commenters also expressed concern that the prominence of the QPA could drive down reimbursement rates for providers that are currently reimbursed above the median contracted rate, which they argued could jeopardize network adequacy and viability of physician practices and, commenters claimed, further drive down the QPA. A number of commenters stated that the emphasis given to the QPA would provide an incentive for plans and issuers to prefer out-of-network care, potentially resulting in reduced networks, because, ultimately, plans and issuers would pay the QPA rather than a market rate driven by the particular circumstances of the care delivered. Commenters also asserted that showing that the QPA is materially different from the appropriate out-of-network rate would burden providers and facilities who lack the resources to gather and submit this information during the Federal IDR process.

Commenters who disagreed with the approach set forth in the October 2021 interim final rules stated that certain provisions created a rebuttable presumption that the QPA is the appropriate out-of-network rate, and these commenters requested that the Departments remove these provisions, and instead issue rulemaking and guidance that instructs certified IDR entities to consider all permissible and relevant information submitted by the parties. Other commenters suggested alternative approaches for the provisions that govern the certified IDR entity's consideration of the enumerated factors. Some commenters requested that equal weight be given to the QPA and the contracted rates between the provider or facility and plan or issuer during the previous 4 years. Other commenters requested that the Departments replace the QPA as the baseline in the Federal IDR process with a different amount, such as the actual amount paid to a particular out-of-network provider for the same or similar item or service or the median contracted rate based on the amount negotiated under each contract the provider has with a plan or issuer.

3. Payment Determinations for Air Ambulance Services

A majority of commenters raised similar points with regard to the Federal IDR process for both non-air ambulance items and services and air ambulance

rate because, for example, modifiers can be used to indicate that the work required to provide a service in a particular instance was significantly greater—or significantly less—than the service typically required. *See* 86 FR 36891.

[23] *See* 86 FR 55997–98.

services. Some supported the emphasis on the QPA, while others disagreed with the use of the QPA as the baseline in the Federal IDR process. These commenters raised concerns about the transparency of the calculation of the QPA, and questioned whether the QPA is the appropriate out-of-network rate. Several commenters stressed that the use of the QPA as a baseline also raises concerns that are unique to air ambulance services. Some commenters highlighted the prevalence of single-case agreements for air ambulance services, which the commenters interpreted as including settlements of post-service claims. The commenters asserted that, because of the prevalence of these agreements, the QPA does not adequately reflect market rates for air ambulance services and the QPA would be lower than appropriate. Other commenters argued that hospital-based providers of air ambulance services are subsidized by the related hospitals, so including the rates of these providers in the QPA calculation with the rates of other air ambulance providers would improperly lower the QPA and therefore the use of the QPA as a baseline would not be appropriate. Another commenter argued that the negotiated rates of the few in-network providers for air ambulance services tend to be inflated by their disproportionately large market power, leading to artificially high air ambulance rates and an inflated QPA value. These commenters proposed that the rules should direct the certified IDR entities to take into account market concentration and prices charged by non-profit affiliated air ambulance providers because air ambulance services owned by private equity and publicly-traded companies receive higher payments and subsequently generate larger and more frequent surprise bills than their non-profit-affiliated counterparts. Other commenters disagreed and stated that the Federal IDR process should not make such a distinction among providers of air ambulance services. One commenter stated that Congress clearly recognized the variation in air ambulance services in distinguishing the six ''additional circumstances'' [24] specific to air ambulance services that certified IDR entities should consider.

4. The Certified IDR Entity's Written Decision

With respect to the certified IDR entity's written decision, several commenters supported the requirement for the certified IDR entity to provide a written decision, including the explanation of the underlying rationale for the certified IDR entity's determination. Other commenters stressed, however, that requiring the explanation of the rationale only if the certified IDR entity determined that the QPA was materially different from the appropriate out-of-network rate could discourage certified IDR entities from considering additional factors. A few commenters requested an explanation be required when the certified IDR entity selected the amount closest to the QPA, including how the information about the other required considerations was assessed while others stated that a robust explanation should be required of the certified IDR entity in all cases. Commenters also stated that requiring an explanation in all cases would ensure that certified IDR entities considered all information submitted by the parties and allow the parties to fully understand the rationale behind the certified IDR entity's determination. Commenters asserted that this could improve the quality and efficiency of the IDR process over time, as parties become better informed as to the types of information certified IDR entities find credible and the circumstances in which the parties should pursue the IDR process. Other commenters requested the Departments either eliminate the requirement for a written decision or require a similar analysis in all written decisions.

E. Litigation Regarding Requirements Related to Surprise Billing; Part II

On October 28, 2021, the Texas Medical Association, a trade association representing physicians, and a Texas physician filed a lawsuit against the Departments and the Office of Personnel Management (OPM), asserting that certain provisions of the October 2021 interim final rules relating to the certified IDR entities' consideration of the QPA, as well as additional factors related to items and services that are not air ambulance services, should be vacated. Plaintiffs argued that the interim final rules ignored Congress's intent that certified IDR entities weigh the QPA and other factors without favoring any factor, and they asserted that, as a result, the rules would skew IDR results in favor of plans and issuers. On February 23, 2022, the United States District Court for the Eastern District of Texas (District Court) issued a memorandum opinion and order that vacated portions of the October 2021 interim final rules governing aspects of the Federal IDR process related to non-air ambulance qualified IDR items or services including: (1) the definition of ''material difference;'' (2) the requirement that a certified IDR entity must select the offer closest to the QPA unless the certified IDR entity determines that credible information submitted by either party under 26 CFR 54.9816–8T(c)(4)(i), 29 CFR 2590.716–8(c)(4)(i), and 45 CFR 149.510(c)(4)(i) clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for non-air ambulance qualified IDR items or services, or if the offers are equally distant from the QPA but in opposing directions; (3) the requirement that the certified IDR entity may only consider the additional information submitted by either party to the extent that the credible information related to the circumstances under 26 CFR 54.9816–8T(c)(4)(i), 29 CFR 2590.716–8(c)(4)(i), and 45 CFR 149.510(c)(4)(i) clearly demonstrates that the QPA is materially different from the appropriate out-of-network rate for non-air ambulance qualified IDR items or services; (4) the dispute resolution examples; and (5) the requirement that, if the certified IDR entity does not choose the offer closest to the QPA, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate, based on the factors certified IDR entities are permitted to consider with respect to the qualified IDR item or service.[25]

On April 27, 2022, LifeNet, Inc., a provider of air ambulance services, filed a lawsuit against the Departments and OPM seeking the vacatur of additional provisions of the October 2021 interim final rules applicable to air ambulance services. In particular, LifeNet alleged that the requirement codified in the last sentence of 26 CFR 54.9817–2T(b)(2), 29 CFR 2590.717–2(b)(2), and 45 CFR

[24] Under section 9817(b)(5)(C) of the Code, section 717(b)(5)(C) of ERISA, and section 2799A–2(b)(5)(C) of the PHS Act, those six additional circumstances are: (1) the quality and outcomes measurements of the provider that furnished such services; (2) the acuity of the individual receiving such services or the complexity of furnishing such services to such individual; (3) the training, experience, and quality of the medical personnel that furnished such services; (4) the ambulance vehicle type, including the clinical capability level of such vehicle; (5) population density of the point of pick-up (such as urban, suburban, rural, or frontier); and (6) 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 and the plan or issuer, as applicable, during the previous 4 plan years.

[25] *Tex. Med. Ass'n, et al.* v. *U.S. Dept. of Health and Human Servs., et al.,* Case No. 6:21–cv–425 (E.D. Tex.).

149.520(b)(2) that the certified IDR entity may consider information submitted by a party only if the information ''clearly demonstrate[s] that the qualifying payment amount is materially different from the appropriate out-of-network rate'' should be vacated. On July 26, 2022, the District Court issued a memorandum opinion and order vacating this language.[26]

F. Scope and Purpose of This Rulemaking

As discussed in more detail later in this preamble, upon review of the comments the Departments received on the information that must be shared about the QPA when a service is downcoded and with respect to the Federal IDR process, and in light of the District Court's memorandum opinions and orders in *Texas Medical Association* and *LifeNet,* the Departments have determined that it is appropriate to issue these final rules to finalize parts of the July 2021 and October 2021 interim final rules related to the information that must be disclosed about the QPA under 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d) to address downcoding; related to the certified IDR entity's consideration of the statutory factors when making a payment determination under the Federal IDR process at 26 CFR 54.9816–8T(c)(4)(iii)–(iv) and 54.9817T–2(b), 29 CFR 2590.716–8(c)(4)(iii)–(iv) and 2590.717–2(b), and 45 CFR 149.510(c)(4)(iii)–(iv) and 149.520(b); and related to the certified IDR entity's written decision at 26 CFR 54.9816–8T(c)(4)(vi)(B), 29 CFR 2590.716–8(c)(4)(vi)(B), and 45 CFR 149.510(c)(4)(vi)(B). These final rules also include changes to remove from the regulations the language vacated by the District Court.

This rulemaking is purposefully narrow in scope and is intended to address only certain issues critical to the implementation and effective operation of the Federal IDR process. The Departments intend to finalize the remaining provisions of the July 2021 and October 2021 interim final rules after further consideration of comments.

II. Overview of Final Rules

A. Information To Be Shared About the Qualifying Payment Amount

As described earlier in this preamble, the July 2021 interim final rules require plans and issuers to make certain disclosures with each initial payment or notice of denial of payment. When the QPA serves as the recognized amount, or as the amount upon which cost sharing is based with respect to air ambulance services, plans and issuers must disclose the QPA and certain information related to the QPA for the item or service involved, as well as certain additional information, upon request of the provider, facility, or provider of air ambulance services for each item or service involved.[27]

As stated in the preamble to the July 2021 interim final rules, the Departments seek to ensure transparent and meaningful disclosure of information relating to the calculation of the QPA for providers, facilities, and providers of air ambulance services, while at the same time minimizing administrative burdens on health plans and issuers and on the Federal IDR process. The Departments sought to balance those competing interests by, on the one hand, requiring plans and issuers to make certain disclosures with each initial payment or notice of denial of payment and to provide certain additional information upon request by the provider, facility, or provider of air ambulance services and, on the other hand, avoiding more wide-reaching disclosure requirements that could add to the costs and burdens of adjudicating claims subject to the surprise billing protections in the No Surprises Act.

After review of the comments submitted on the July 2021 interim final rules regarding downcoding and on the clarification in the preamble to the October 2021 interim final rules stating that, under the July 2021 interim final rules, a plan or issuer may calculate the QPA using a downcoded service code, including the comments suggesting how the disclosure requirements could be modified in light of this clarification, the Departments have concluded that additional disclosure of information about the QPA is appropriate.[28] This additional disclosure will ensure that providers, facilities, and providers of air ambulance services receive information regarding the QPA that aids in their meaningful participation in open negotiation and the Federal IDR process in all payment disputes that involve qualified items or services that have been subject to downcoding.

Specifically, the Departments are of the view that additional information would be helpful in cases in which the plan or issuer has downcoded the billed claim to ensure that providers, facilities, and providers of air ambulance services receive the relevant information from a plan or issuer that is needed to engage in a productive open negotiation period. Without information on what the QPA would have been had the claim not been downcoded, the provider, facility, or provider of air ambulance services may be at a disadvantage compared to the plan or issuer. In cases in which the plan or issuer has downcoded the billed claim and asserts that the QPA that corresponds with the downcoded claim is the correct total payment amount, it is of particular importance that the provider, facility, or provider of air ambulance services knows that the item or service in question has been downcoded and has information regarding both the QPA for the downcoded claim and the amount that would have been the QPA had the service code or modifier not been downcoded. In the Departments' view, this information may be critical to the provider, facility, or provider of air ambulance services in developing an offer or submitting information if it believes that the QPA calculated by the plan or issuer does not best represent the value of the item or service provided.

Furthermore, the requirement to disclose this additional information will increase transparency by ensuring that the provider, facility, or provider of air ambulance services has sufficient information about the QPA to submit an informed offer, including how it relates to the billed claim. This increased transparency will aid in the open negotiation process by helping providers, facilities, and providers of air ambulance services to understand how the plan or issuer arrived at the relevant QPA in relation to the billed claim. This increased transparency will inform the provider's, facility's, or provider of air ambulance services' decision whether to initiate open negotiation and the Federal IDR process, as well as its determination of the amount that it submits as its offer.[29] Further, this requirement will help a provider, facility, or provider of air ambulance services ascertain what information to provide the certified IDR entity to demonstrate that the provider's, facility's, or provider of air ambulance

[26] *LifeNet, Inc.* v. *United States Department of Health and Human Services, et al.,* Case No. 6:22–cv–162 (E.D. Tex.).

[27] 26 CFR 54.9816–6T(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d).

[28] 86 FR 55997–98 (October 7, 2021).

[29] The Departments understand that many plans and issuers make initial payments that are equivalent to or are informed by the corresponding QPA for the item or service at issue. As noted in in the preamble to the July 2021 interim final rules, the initial payment should be an amount that the plan or issuer reasonably intends to be payment in full based on the relevant facts and circumstances, which may be higher or lower than the QPA, as required under the terms of the plan or coverage, prior to the beginning of any open negotiation or initiation of the Federal IDR process. 86 FR 36872, 36900 (July 13, 2021).

services' offer best represents the value of the item or service. If submitted for the certified IDR entity's consideration, this information will also aid the certified IDR entity in selecting the offer that best represents the value of the item or service by ensuring that the certified IDR entity will have additional pertinent information about the item or service. For example, in a dispute that concerns a qualified IDR service for which the plan or issuer downcoded the billed service code, the provider, facility, or provider of air ambulance services may present information showing that the billed service code was more appropriate than the downcoded service code. In such an instance, the certified IDR entity could determine that the QPA based on the downcoded service code does not sufficiently encompass the complexity of furnishing the qualified IDR service because it was based on a service code for a different service from the one furnished. If the certified IDR entity makes such a determination, then the amount that would have been the QPA had the service code or modifier not been downcoded may be relevant to the certified IDR entity in determining which offer best represents the value of the qualified IDR item or service.

Therefore, the Departments are issuing these final rules to add a definition for the term ''downcode'' to 26 CFR 54.9816–6, 29 CFR 2590.716–6, and 45 CFR 149.140; and final rules under 26 CFR 54.9816–6(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d) to require additional information about the QPA that must be provided with an initial payment or notice of denial of payment, without a provider, facility, or provider of air ambulance services having to make a request for this information, in cases in which the plan or issuer has downcoded the billed claim. Although ''downcoding'' is being defined for the first time in these final rules, the concept was reflected in both sets of interim final rules. Though neither set of interim final rules specifically defines a term for this practice, the interim final rules described the practice and explained that it was permissible under certain circumstances. See 86 FR 55997–98 n.35 (clarification in October 2021 interim final rules regarding requirements of July 2021 interim final rules). Indeed, as described previously, the Departments received several comments in response to the July 2021 interim final rules and the October 2021 interim final rules requesting that the disclosures that must be provided with each initial payment or notice of denial of payment include additional information about how the QPA was calculated to ensure that providers, facilities, and providers of air ambulance services have sufficient information when the Federal IDR process is used for a payment determination. For example, commenters requested that plans and issuers be required, without a request, to provide information on the number of contracts and the geographic region used to calculate the QPA, whether the QPA was calculated based on a downcoded billed claim, information about the use of modifiers in calculating the QPA, the types of specialties and subspecialties that have contracted rates included in the data set used to determine the QPA, and whether bonuses and supplemental payments were paid to in-network providers.

These final rules define the term ''downcode,'' as described in the preamble to the October 2021 interim final rules, to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

These final rules also specify that, if a QPA is based on a downcoded service code or modifier, in addition to the information already required to be provided with an initial payment or notice of denial of payment, a plan or issuer must provide a statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and which modifiers were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded.

The Departments are continuing to consider comments on the July 2021 interim final rules about whether additional disclosures related to the QPA calculation methodology should be required to be provided with an initial payment or notice of denial of payment, or upon request. The Departments note that the statute places the responsibility for monitoring the accuracy of plans' and issuers' QPA calculation methodologies with the Departments (and applicable state authorities) by requiring audits of plans' and issuers' QPA calculation methodologies,[30] and the Departments have committed to conducting audits. The Departments also stress that payment determinations in the Federal IDR process should center on a determination of a total payment amount for a particular item or service based on the facts and circumstances of the dispute at issue, rather than an examination of a plan's or issuer's QPA methodology.

B. Payment Determinations Under the Federal IDR Process

The October 2021 interim final rules provide that, not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer or the provider, facility, or provider of air ambulance services as the out-of-network rate for the qualified IDR item or service. In determining which offer to select, the October 2021 interim final rules provided, prior to *Texas Medical Association* and *LifeNet,* that the certified IDR entity must first look to the QPA, as it represents a reasonable market-based payment for relevant items and services, and then to additional information requested by the certified IDR entity from the parties and other additional information submitted by the parties. After considering the QPA and additional information, the October 2021 interim final rules required the certified IDR entity to select the offer closest to the QPA, unless the certified IDR entity determined that the additional information requested by the certified IDR entity and the credible information submitted by the parties demonstrated that the QPA was materially different from the appropriate out-of-network rate, or if the offers were equally distant from the QPA but in opposing directions. In instances in which the certified IDR entity determined that the credible information submitted by the parties clearly demonstrated that the QPA was materially different from the appropriate out-of-network rate, or when the offers were equally distant from the QPA but in opposing directions, the October 2021 interim final rules state that the certified IDR entity must select the offer that the certified IDR entity determined best represents the value of the item or service, which could be either party's offer.

As stated earlier in this preamble, on February 23, 2022 and July 26, 2022, the District Court in *Texas Medical Association* and *LifeNet* issued memorandum opinions and orders that vacated certain provisions of the October 2021 interim final rules that govern aspects of the Federal IDR process, including provisions that

[30] 86 FR 36872, 36899 (July 13, 2021).

provided guidance to certified IDR entities on selecting the appropriate out-of-network rate in a payment determination. In the October 2021 interim final rules, the Departments required certified IDR entities to view the QPA as an appropriate payment amount, subject to consideration of the information submitted by the parties related to the additional circumstances outlined in the statute, as a mechanism to ensure that certified IDR entities approached making payment determinations in the Federal IDR process in a consistent manner. The regulatory text required certified IDR entities to select the offer closest to the QPA unless the certified IDR entity determined that credible information submitted by a party clearly demonstrated that the QPA was materially different from the appropriate out-of-network rate. The preamble to the October 2021 interim final rules described the relevant instructions to certified IDR entities as a ''rebuttable presumption'' in favor of the QPA.

The District Court in *Texas Medical Association* and *LifeNet* vacated the portions of the October 2021 interim final rules that it construed as creating a rebuttable presumption in favor of the QPA. The Departments note that these final rules are not intended to impose a rebuttable presumption for payment determinations in the Federal IDR process. The regulatory text in these final rules does not include the provisions that the District Court reasoned would have the effect of imposing such a presumption.

The Departments note that, in all cases, the QPA, which is generally based on the median contracted rate for a qualified IDR item or service, will be relevant to a payment determination, as it represents the typical payment amount that a plan or issuer that is a party to a payment determination will pay in-network providers, facilities, and providers of air ambulance services for that particular qualified IDR item or service. The Departments also note that, to the extent the QPA is calculated in a manner that is consistent with the detailed rules issued under the July 2021 interim final rules, and is communicated in a way that satisfies the applicable disclosure requirements, the QPA will meet the credibility requirement that applies to the additional information and circumstances set forth in these final rules.[31] The credibility requirement is designed to ensure that the additional information submitted by the parties to a payment determination meet the same credibility standard that the QPA already meets through other mechanisms, by virtue of the requirements related to the QPA set forth in the July 2021 interim final rules. The Departments also note that the credibility requirement is designed to ensure that certified IDR entities have clear guidance on how to evaluate potentially voluminous and complex information in a methodical and consistent manner. Absent clear guidance on a process for evaluating the different factors, there would be no guarantee of consistency in how certified IDR entities reached determinations in different cases. The Departments are of the view that this guidance is also important because the QPA must be a quantitative figure, like the offers that will be submitted in a payment determination. Generally, these quantitative figures will be unlike the information received related to the additional circumstances, which will often be qualitative and open to subjective evaluation. Although the QPA is a quantitative figure, the amount that best represents the value of the qualified IDR items and services may be more or less than the QPA due to additional circumstances that are not easily quantifiable such as the care setting or the teaching status of the facility. It therefore is reasonable to ensure that certified IDR entities consider the QPA, a quantitative figure, and then consider the additional, likely-qualitative factors, when determining the out-of-network rate—another quantitative figure.

1. Requirement To Consider the QPA and Additional Information Submitted

In light of the *Texas Medical Association* and *LifeNet* decisions, and in response to comments received on these provisions, the Departments are finalizing rules that remove the provisions that the District Court vacated and that adopt standards for making a payment determination that are intended to achieve the statutory aims articulated earlier in this preamble.

Congress granted the Departments statutory authority to ''establish by regulation one independent dispute resolution process'' under which certified IDR entities determine the amount of payment for an out-of-network item or service.[32] The Federal IDR process that the Departments establish under this authority is to be ''in accordance with the succeeding provisions of'' the cited statutory subsections,[33] including the statutory provisions describing the factors for the certified IDR entity to consider in determining the out-of-network payment amount. Under sections 9816(c)(5) and 9817(b)(5) of the Code, sections 716(c)(5) and 717(b)(5) of ERISA, and sections 2799A–1(c)(5) and 2799A–2(b)(5) of the PHS Act, the statute provides that with respect to payment determinations, the certified IDR entity must always consider the QPA without the parties specifically bringing it to the certified IDR entity's attention. Next, the statute provides that the certified IDR entity must also consider ''additional information'' or ''additional circumstances'' submitted to the certified IDR entity.

As explained later in this preamble, the Departments are of the view that it is appropriate to exercise their authority under this provision, and that it is in accordance with these statutory provisions, to adopt a Federal IDR process that encourages a consistent methodology for evaluation of information when making a payment determination. The Departments are of the view that there is value in ensuring that all certified IDR entities approach payment determinations in a similar manner, which will promote consistency and predictability in the process, thereby lowering administrative costs and encouraging consistency in appropriate payments for out-of-network services.[34] The statute requires certified IDR entities to always consider the QPA when making a payment determination, as it is the one statutory consideration that will always be present in each payment determination, whereas the parties may or may not choose to submit

[31] To the extent there is a question whether a plan or issuer has complied with the July 2021 interim final rules' requirements for calculating the QPA, it is the Departments' (or applicable State authorities') responsibility, not the certified IDR entity's, to monitor the accuracy of the plan's or issuer's QPA calculation methodology by conducting an audit of the plan's or issuer's QPA calculation methodology. However, a provider or facility may always assert to the certified IDR entity that additional information points in favor of the selection of its offer as the out-of-network payment amount, even where that offer is for a payment amount that is different from the QPA.

[32] *See* section 9816(c)(2)(A) of the Code, section 716(c)(2)(A) of ERISA, and section 2799A–1(c)(2)(A) of the PHS Act; *see also* section 9817(b)(2)(A) of the Code, section 717(b)(2)(A) of ERISA, and section 2799A–2(b)(2)(A) of the PHS Act.

[33] *Id.*

[34] *See* Cong. Budget Office, *H R. 5826, the Consumer Protections Against Surprise Medical Bills Act of 2020, as Introduced on February 10, 2020: Estimated Budgetary Effects* at 1 (Feb. 11, 2020) (arbitrators ''would be instructed to look to the health plan's median payment rate for in-network rate care,'' and as a result ''average payment rates for both in- and out-of-network care would move toward the median in-network rate,'' thereby lowering health insurance premiums and budget deficits); *see also* H.R. Rep. No. 116–615, pt. I, at 57–58 (2020).

information related to the additional circumstances as part of their offer. Consideration of the QPA, which is the first-listed statutory factor and a quantitative figure, will aid certified IDR entities in their consideration of each of the other statutory factors, as these entities will then be in a position to evaluate whether the ''additional'' factors present information that may not have already been captured in the calculation of the QPA.

As commenters noted, there may be instances in which the QPA would not adequately account for one or more of the additional factors. The Departments note that these final rules do not require certified IDR entities to default to the offer closest to the QPA or to apply a presumption in favor of that offer. The Departments are of the view that it will often be the case that the QPA represents an appropriate out-of-network rate, as the QPA is largely informed by similar information to what would be provided as information in support of the additional statutory circumstances. Nonetheless, the Departments acknowledge that the additional factors may be relevant in determining the appropriate out-of-network rate, because the QPA may not account for information specific to a particular item or service. Therefore, these final rules do not require the certified IDR entity to select the offer closest to the QPA. Rather, these final rules specify that certified IDR entities should select the offer that best represents the value of the item or service under dispute after considering the QPA and all permissible information submitted by the parties.

Accordingly, in determining which offer to select during the Federal IDR process under these final rules, the certified IDR entity must consider the QPA for the applicable year for the same or similar item or service and then must consider all additional information submitted by a party to determine which offer best reflects the appropriate out-of-network rate, provided that the information relates to the party's offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (and does not include information that the certified IDR entity is prohibited from considering in making the payment determination under section 9816(c)(5)(D) of the Code, section 716(c)(5)(D) of ERISA, and section 2799A–1(c)(5)(D) of the PHS Act).[35] For this purpose, the Departments understand that information requested by a certified IDR entity, or submitted by a party, would be information relating to a party's offer if it tends to show that the offer best represents the value of the item or service under dispute. Therefore, these rules require the certified IDR entity to evaluate whether the information relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In considering this additional information, the certified IDR entity should evaluate whether information that is offered is credible and should not give weight to information that is not credible.[36] The appropriate out-of-network rate must be the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.

For non-air ambulance items and services, the additional information to be considered includes information related to the following factors:

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; and

5. the 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.

Under these final rules, the certified IDR entity must also consider information related to the offer provided in response to a request from the certified IDR entity under 26 CFR 54.9816–8T(c)(4)(i)(A)(*2*), 29 CFR 2590.716–8(c)(4)(i)(A)(*2*), and 45 CFR 149.510(c)(4)(i)(A)(*2*).

2. Avoidance of Double-Counting Information

When considering the additional information under 26 CFR 54.9816–8(c)(4)(iii), 29 CFR 2590.716–8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii), the certified IDR entity should evaluate the information and should not give weight to that information if it is already accounted for by any of the other information submitted by the parties. The certified IDR entity should consider whether the additional information is already accounted for in the QPA and should not give weight to information related to a factor if the certified IDR entity determines the information was already accounted for in the calculation of the QPA, to avoid weighting the same information twice. In addition, if the parties submit information related to more than one of the additional factors, the certified IDR entity should also consider whether the information submitted regarding those factors is already accounted for by information submitted relating to other credible information submitted to the certified IDR entity in relation to another factor and, if so, should not weigh this information more than once.

Numerous comments received on the October 2021 interim final rules highlighted that, in many cases, certain factors, such as patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee, will already be accounted for in the calculation of the QPA and should therefore not receive additional weight. For example, because the plan or issuer is required to calculate the QPA using median contracted rates for service codes, as well as modifiers (if applicable), and because service codes and modifiers in many cases reflect patient acuity and the complexity of the service provided, these factors will often already be reflected in the QPA.

Commenters also acknowledged that there could be instances in which the QPA would not adequately account for the acuity of the patient or complexity of the service: for example, if the complexity of a case is an outlier such that the time or intensity of care exceeds what is typical for a service code. A certified IDR entity may also conclude that the QPA does not already account for patient acuity or the complexity of furnishing the qualified IDR item or service in instances where the parties disagree on what service code or modifier accurately describes the qualified IDR item or service, such as when a plan or issuer has downcoded a claim and the QPA is based on the

[35] *See also* 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v).

[36] For this purpose, credible information is information that upon critical analysis is worthy of belief and is trustworthy. 26 CFR 54.9816–8T(a)(2)(v), 29 CFR 2590.716–8(a)(2)(v), and 45 CFR 149.510(a)(2)(v).

downcoded service code or modifier, rather than the billed service code or modifier.

The Departments agree with the commenters that, in many cases, the additional factors for the certified IDR entity to consider other than the QPA will already be reflected in the QPA. The QPA is generally calculated to include characteristics that affect costs, including medical specialty, geographic region, and patient acuity and case severity, all captured in different billing codes or the QPA calculation methodology.[37] Therefore, in the Departments' view, giving additional weight to information that is already incorporated into the calculation of the QPA would be redundant, possibly resulting in the selection of an offer that does not best represent the value of the qualified IDR item or service and potentially over time contributing to higher health care costs. As noted earlier in this preamble, the Departments are also aware that there are instances when certain factors related to the qualified IDR item or service may not be adequately reflected in the QPA. Under these final rules, certified IDR entities are required to consider the QPA and then must consider all additional information submitted by the parties relating to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination, but each factor should be weighted only once in the evaluation of each party's payment offer. To the extent a factor is not already reflected in the QPA, the certified IDR entity should accord that factor appropriate weight based on information related to it provided by the parties. For example, some providers and facilities that provide high-acuity care, such as level 1 trauma or neonatal care, may contend that additional factors such as their case mix and the scope of services offered were not accounted for in the QPA and could justify the selection of a higher amount as the out-of-network payment amount.

3. Examples Provided

These final rules also include examples to illustrate the consideration of factors when making a payment determination, including whether and how to give weight to additional information submitted by a party. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, including the applicable QPA(s), and the submitted information does not include information on the prohibited factors.

In the first new example, a level 1 trauma center that is a nonparticipating emergency facility submits an offer that is higher than the QPA. Along with the offer, the nonparticipating emergency facility submits additional written information showing that the scope of services available at the nonparticipating emergency facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity, and the information is determined to be credible by the certified IDR entity. The nonparticipating emergency facility also submits information showing that the contracted rates used to calculate the QPA were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the QPA. No additional information is submitted by either party. The certified IDR entity determines that the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that this information demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

In the second new example, a nonparticipating provider submits an offer that is higher than the QPA. Along with the offer, the nonparticipating provider submits additional written information regarding the level of training and experience of the provider, and the information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the provider does not demonstrate that the level of training and experience relates to the offer for the appropriate payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the level of training and experience was necessary to provide the qualified IDR service or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an amount equal to the QPA as its offer, with no additional information. Even if the certified IDR entity determines that the additional information regarding the level of training and experience is credible, if the certified IDR entity determines that the information does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, the certified IDR entity should not give weight to the additional information. In the absence of any other credible information that relates to a party's offer, the certified IDR entity should select the issuer's offer as the offer that best represents the value of the qualified IDR service.

In the third new example, in connection with an emergency department visit for the evaluation and management of a patient, a nonparticipating provider submits an offer that is higher than the QPA. Along with the offer, the nonparticipating provider submits additional written information showing that the acuity of the patient's condition and the complexity of the qualified IDR service required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity, and the information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the QPA for Current Procedural Terminology (CPT) code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition, and the information is determined to be credible by the certified IDR entity. The certified IDR entity determines that this information relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. Neither party submits any additional information. If the certified IDR entity determines the information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the QPA, the certified IDR entity should not

[37] Plans and issuers are required to calculate separate QPAs for the same service code by provider specialty if the plan or issuer has contracted rates for the service code that vary based on provider specialty. *See* 26 CFR 54.9816–6T(b)(3), 29 CFR 2590.716–6(b)(3), and 45 CFR 149.140(b)(3).

give weight to the additional information provided by the nonparticipating provider. If, after evaluating the information submitted by the parties, the IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, then the certified IDR entity should select the issuer's offer.

In the fourth new example, the issuer submits an offer that is higher than the QPA and that is equal to the nonparticipating emergency facility's prior contracted rate (adjusted for inflation) with the issuer for the previous year for the qualified IDR service. Although the facility is not participating in the issuer's network this year, it was a participating facility in the issuer's network in the previous 4 plan years. Along with the offer, the issuer submits additional written information showing that the contracted rates between the nonparticipating facility and the issuer during the previous 4 plan years were higher than the QPA, and that these prior contracted rates took into account the case mix and scope of services typically furnished at the facility. The certified IDR entity determines that the information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. The nonparticipating emergency facility submits an offer that is higher than both the QPA and the prior contracted rate (adjusted for inflation) and submits additional written information intending to show that the case mix and scope of services available at the facility that furnished the qualified IDR service were integral to the services provided. The certified IDR entity determines this information is credible and relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information that the issuer submitted regarding prior contracted rates, then that same information that has been submitted twice should be weighted only once by the certified IDR entity. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

In the fifth new example, regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed, the issuer submits an offer equal to the QPA (which was calculated using the downcoded service code). The issuer also submits the additional written information that it was required to disclose to the nonparticipating provider at the time of the initial payment. The certified IDR entity determines the additional information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The nonparticipating provider submits an offer equal to the amount that would have been the QPA had the service code not been downcoded. The nonparticipating provider submits additional written information that includes the same documentation provided by the issuer, as well as information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer best represents the value of the service furnished, given its complexity. Neither party submits any additional information. The certified IDR entity determines that the information submitted by the provider is credible and that it is related to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the provider and that this information demonstrates that the provider's offer best represents the value of the qualified IDR service, the certified IDR entity should select the provider's offer.

The Departments note that the statute and the October 2021 interim final rules continue to provide that when making a payment determination, a certified IDR entity must not consider information on the prohibited factors, such as the usual and customary charges (including payment or reimbursement rates expressed as a proportion of usual and customary charges); the amount that would have been billed by the provider, facility, or provider of air ambulance services with respect to the qualified IDR item or service had the balance billing provisions of 45 CFR 149.410, 149.420, and 149.440 (as applicable) not applied; or the payment or reimbursement rate for items and services furnished by the provider, facility, or provider of air ambulance services payable by a public payor.[38 39] In considering all the permissible information submitted by the parties, the Departments expect that the certified IDR entity will conduct a thorough review of the information submitted to evaluate whether the information includes any of the prohibited factors, so as to ensure that prohibited factors are not considered in any payment determinations. In conducting this review, the certified IDR entity may request additional information from the disputing parties, including confirmation that information submitted does not include information on the prohibited factors.

The Departments are committed to establishing a fair, cost-effective, and reasonable IDR payment determination process that does not have an inflationary impact on health care costs. To that end, the Departments will monitor the effects of these payment determination requirements and make appropriate adjustments as necessary to achieve the intended goals articulated in this preamble.

C. Payment Determinations Under the Federal IDR Process for Air Ambulance Services

As discussed in section I.C of this preamble, the process for a certified IDR entity to select an offer in a dispute

[38] Contracted rates are frequently based on a percentage of rates payable by a public payor, such as Medicare. In these cases, because contracting parties have chosen to set their rates in this way, the contracted rates represent an independent decision by contracting parties. Thus, if a party submits information on such rates to a certified IDR entity, consideration of these contracted rates does not violate the prohibition on considering the factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), and 45 CFR 149.510(c)(4)(v). In contrast, if a party submits evidence showing that its offer was a percentage of the rates paid by Medicare, a certified IDR entity is prohibited from considering such information.

[39] Under 5 U.S.C. 8904(b), in the case of a retired individual who is over age 65 and enrolled in the Federal Employees Health Benefits (FEHB) Program but not covered by Medicare part A or B, fee-for-service FEHB carriers may not pay a charge imposed by a hospital provider for inpatient services or a physician to the extent that charge exceeds applicable Medicare limits. The Departments, after consulting with OPM, clarify that a certified IDR entity is not considered to violate the prohibition on considering the payment or reimbursement rate for items and services furnished by the provider, facility, or provider of air ambulance services payable by a public payor to the extent the certified IDR entity's selection of an offer is made to allow compliance with 5 U.S.C. 8904(b) and 5 CFR part 890, subpart I. That is, if 5 U.S.C. 8904(b) applies, and either offer exceeds the applicable Medicare limit referenced in 5 U.S.C. 8904(b), the certified IDR entity must ensure that the payment determination does not exceed the applicable Medicare limit. A certified IDR entity would not be considered to violate the prohibition on considering Medicare reimbursement rates when it selects an offer on this basis.

related to qualified IDR services that are air ambulance services is generally the same as the process applicable to disputes related to qualified IDR items or services that are not air ambulance services. However, section 9817(b)(5)(C) of the Code, section 717(b)(5)(C) of ERISA, section 2799A–2(b)(5)(C) of the PHS Act, and the October 2021 interim final rules specify different additional circumstances, in addition to the QPA, that the certified IDR entity must consider in making the payment determination for air ambulance services. Upon review of the comments the Departments received on the Federal IDR process, and in light of the District Court's memorandum opinions and orders in *Texas Medical Association* and *LifeNet,* the Departments have determined that it is appropriate to issue the final rules under the Federal IDR process for air ambulance services.

As for non-air ambulance items and services, these final rules provide that in determining which offer to select in a dispute related to air ambulance services, the certified IDR entity must consider certain additional information submitted by a party. Also, for non-air ambulance items and services, these final rules for air ambulance services provide that the certified IDR entity must consider the QPA for the applicable year for the same or similar service and then consider all additional permissible information to determine the appropriate out-of-network rate. For air ambulance services, this information includes information related to the following factors:

1. quality and outcomes measurements of the provider that furnished the services;
2. the acuity of the condition of the participant, beneficiary, or enrollee receiving the service, or the complexity of furnishing the service to the participant, beneficiary, or enrollee;
3. training, experience, and quality of the medical personnel that furnished the air ambulance service;
4. ambulance vehicle type, including the clinical capability level of the vehicle;
5. population density of the point of pick-up; and
6. demonstrations of good faith efforts (or lack thereof) by the disputing parties to enter into network agreements with each other, as well as, if applicable, contracted rates between the parties during the previous 4 plan years.

Additionally, as with non-air ambulance disputes, the certified IDR entity must also consider information related to the offer provided in a response to the certified IDR entity's request under 26 CFR 54.9816–8T(c)(4)(i)(A)(*2*), 29 CFR 2590.716–8(c)(4)(i)(A)(*2*), and 45 CFR 149.510(c)(4)(i)(A)(*2*). The certified IDR entity must also consider other information provided by the parties under 26 CFR 54.9816–8(c)(4)(iii)(D), 29 CFR 2590.716–8(c)(4)(iii)(D), and 45 CFR 149.510(c)(4)(iii)(D).

As with non-air ambulance disputes, the certified IDR entity should evaluate whether each piece of submitted information is credible, relates to the offer for the payment amount for the qualified IDR service submitted by either party, and does not include information on factors described in 26 CFR 54.9816–8T(c)(4)(v), 29 CFR 2590.716–8(c)(4)(v), or 45 CFR 149.510(c)(4)(v) (regarding prohibited considerations). When considering the additional information listed above, the certified IDR entity should not give weight to the information to the extent it is not credible, does not relate to either party's offer for the payment amount for the qualified IDR service, or is included in the QPA calculation or other credible information. The Departments note that these final rules do not require certified IDR entities to default to the offer closest to the QPA or to apply a presumption in favor of that offer. Rather, these final rules specify that certified IDR entities should select the offer that best represents the value of the air ambulance service under dispute after considering the QPA and all permissible information submitted by the parties.

D. The Certified IDR Entity's Written Decision

Under section 9816(c)(7) of the Code, section 716(c)(7) of ERISA, and section 2799A–1(c)(7) of the PHS Act, the Departments are required to publish a variety of information relating to the Federal IDR process, including the number of times a payment amount determined or agreed to under this process exceeds the QPA; the amount of each offer submitted in the Federal IDR process expressed as a percentage of the QPA; and any other information specified by the Departments. The statute also instructs certified IDR entities to submit to the Departments such information as the Departments determine necessary to carry out the provisions of section 9816(c) of the Code, section 716(c) of ERISA, and section 2799A–1(c) of the PHS Act, which include these reporting requirements as well as the Departments' obligations to establish and oversee the Federal IDR process. The Departments have determined it is necessary under this provision to require certified IDR entities to submit certain information, including a written statement of the certified IDR entity's reasons for a particular determination of an out-of-network rate.

Under the October 2021 interim final rules, the certified IDR entity must explain its payment determination and the underlying rationale in a written decision submitted to the parties and the Departments, in a form and manner specified by the Departments. The October 2021 interim final rules also required the certified IDR entity to include in its written decision an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate if the certified IDR entity did not choose the offer closest to the QPA.

As stated earlier in this preamble, on February 23, 2022, the District Court in *Texas Medical Association* issued a memorandum opinion and order that invalidated the requirement to provide an explanation of the credible information that the certified IDR entity determined demonstrated that the QPA was materially different from the appropriate out-of-network rate (but not the general requirement that a certified IDR entity issue a written decision). The Departments are of the view that, in all cases, a written decision with a comprehensive discussion of the rationale for the decision is important to ensure that the parties understand the outcome of a payment determination under the Federal IDR process. The Departments note that commenters generally supported the requirement that certified IDR entities provide a written rationale for determinations. The Departments agree with commenters' assertions that the certified IDR entity should be required to provide an explanation for its decision in all cases, and not only when the offer furthest from the QPA is determined to best represent the value of the qualified IDR item or service. This requirement will ensure that all parties understand the certified IDR entity's payment determination and how the various information was considered.

The Departments are finalizing standards for the written decision that are intended to achieve transparency and consistency in the Federal IDR process. Accordingly, similar to the October 2021 interim final rules these final rules require that the certified IDR entity explain in all cases its determination in a written decision provided to the parties and the Departments, in a form and manner specified by the Departments in separate guidance. Additionally, these final rules

continue to require that the rationale be included in the written decision. In response to comments requesting additional transparency and explanation, these final rules also provide that the certified IDR entity's written decision must include an explanation of its determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted in accordance with these final rules. This requirement will help ensure that certified IDR entities carefully evaluate all credible information and promote transparency with respect to payment determinations. These final rules also provide that, if the certified IDR entity relies on additional information or additional circumstances in selecting an offer, its written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the QPA. The Departments are of the view that, in these cases, the certified IDR entity should provide this additional explanation so that the Departments may fulfill their statutory functions to monitor and to report on how often, and why, an offer that is selected exceeds the QPA for a given qualified IDR item or service. Additionally, this requirement will provide the Departments with valuable information to inform future policy making, in particular, policy making related to the QPA methodology. As stated elsewhere in this preamble, the Departments are committed to establishing a reasonable and fair Federal IDR process.

Finally, the Departments are also including two technical corrections to address a regulatory cross-references in the provisions that set forth the requirements for the certified IDR entity to include a rationale for its written decision for both air ambulance and non-air ambulance qualified IDR items and services in monthly reporting to the Departments, and to clarify that the certified IDR entity should report to the Departments the extent to which the decision relied on 26 CFR 54.9816–8(c)(4)(iii)(B)–(D), 29 CFR 2590.716–8(c)(4)(iii)(B)–(D), and 45 CFR 149.510(c)(4)(iii)(B)–(D). This requirement aligns the reporting requirement with the requirement for the written decision, and with the intent of the October 2021 interim final rules to gather such information.

III. Applicability of the Final Rules

These rules finalize certain provisions of the July 2021 and October 2021 interim final rules and address the decisions in *Texas Medical Association* and *LifeNet.* The July 2021 and October 2021 interim final rules apply for plan years (in the individual market, policy years) beginning on or after January 1, 2022, except to the extent provided below.

The final rules that implement the requirements related to the additional information that must be provided with each initial payment or notice of denial of payment if the QPA is based on a downcoded service code or modifier are applicable with respect to items or services furnished on or after October 25, 2022, for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

With respect to the additional information that must be provided with each initial payment or notice of denial of payment if a QPA is based on a downcoded service code or modifier, the Departments recognize that plans and issuers often provide these notices through an automated or other streamlined system for efficiency and that plans and issuers may need additional time to update their operating systems to amend the notices that are currently generated to satisfy the QPA disclosure requirements under the July 2021 interim final rules. Plans and issuers may use reasonable methods to provide this additional disclosure with the initial payment or notice of denial of payment while plan or issuer systems and procedures are updated to provide the additional notice in a more streamlined and automated manner. Even when using other reasonable methods, plans and issuers must provide the required information starting on the date these final rules are applicable to the relevant plan or policy and in accordance with the timeframes specified in the July 2021 interim final rules. The Departments expect that plans and issuers will work to make sure that systems are updated in a timely fashion, and the Departments may provide additional guidance, as warranted.

For requirements that finalize certain provisions of the October 2021 interim final rules, the final rules addressing the payment determination standards for certified IDR entities, written decisions, and reporting are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years (in the individual market, policy years) beginning on or after January 1, 2022. This approach will ensure uniformity and predictability in standards for qualified IDR items and services (including between non-air ambulance items and services and air ambulance services, to the extent applicable), and will allow time for the Departments to provide updated guidance to certified IDR entities and stakeholders.

If any provision in this rulemaking is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, the provision shall be severable from the remainder of this rulemaking, and shall not affect the remainder thereof, and the invalidation of any specific application of a provision shall not affect the application of the provision to other persons or circumstances.

IV. Regulatory Impact Analysis

A. Summary

The Departments have examined the effects of these final rules as required by Executive Order 12866,[40] Executive Order 13563,[41] the Paperwork Reduction Act of 1995,[42] the Regulatory Flexibility Act,[43] section 202 of the Unfunded Mandates Reform Act of 1995,[44] Executive Order 13132,[45] and the Congressional Review Act.[46]

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive order defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity,

[40] Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

[41] Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

[42] 44 U.S.C. 3506(c)(2)(A) (1995).

[43] 5 U.S.C. 601 *et seq.* (1980).

[44] 2 U.S.C. 1501 *et seq.* (1995).

[45] Federalism, 64 FR 153 (Aug. 4, 1999).

[46] 5 U.S.C. 804(2) (1996).

competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order. Based on the Departments' estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is ''economically significant'' under section 3(f)(1) of Executive Order 12866 as measured by the $100 million threshold.[47] Therefore, the Departments have prepared a Regulatory Impact Analysis that presents the costs, benefits, and transfers associated with this rulemaking. Pursuant to the Congressional Review Act, OMB has designated these final rules as a ''major rule,'' as defined by 5 U.S.C. 804(2).

C. Need for Regulatory Action

On December 27, 2020, the CAA, which includes the No Surprises Act, was enacted.[48] The No Surprises Act provides Federal protections against surprise billing by limiting out-of-network cost sharing and prohibiting balance billing in many of the circumstances in which surprise bills arise most frequently.

On July 13, 2021, the Departments published the July 2021 interim final rules.[49] The July 2021 interim final rules implemented provisions of the No Surprises Act to protect participants, beneficiaries, and enrollees in group health plans and group and individual health insurance coverage from surprise medical bills when they receive emergency services, non-emergency services furnished by nonparticipating providers with respect to patient visits to certain participating facilities, and air ambulance services provided by nonparticipating providers of air ambulance services.

On October 7, 2021, the Departments published the October 2021 interim final rules.[50] The October 2021 interim final rules build on the July 2021 interim final rules and implement the Federal IDR process.[51] The October 2021 interim final rules generally apply to group health plans and health insurance issuers offering group or individual health insurance coverage (including grandfathered health plans) with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022; and to health care providers and facilities, providers of air ambulance services, and certified IDR entities beginning on January 1, 2022 with respect to items and services furnished during a plan year (in the individual market, policy year) beginning on or after January 1, 2022.

On February 23, 2022, the District Court in *Texas Medical Association* issued a memorandum opinion and order that vacated portions of the October 2021 interim final rules governing aspects of the Federal IDR process, as discussed earlier in this preamble. On July 26, 2022, the District Court in *LifeNet* issued a memorandum opinion and order that vacated additional portions of the October 2021 interim final rules, as discussed earlier in this preamble.

In response to the decisions in *Texas Medical Association* and *LifeNet* and comments received on the October 2021 interim final rules and July 2021 interim final rules, these final rules address certain issues critical to the implementation and effective operation of the Federal IDR process, including the disclosure requirements relating to information that group health plans and health insurance issuers offering group or individual health insurance coverage must share about the QPA, and certain requirements related to consideration of information when a certified IDR entity makes a payment determination under the Federal IDR process.

i. Final Rules on Information To Be Shared About the Qualifying Payment Amount

As described earlier in this preamble, the July 2021 interim final rules require plans and issuers to make certain disclosures with each initial payment or notice of denial of payment in cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility, or the amount upon which cost sharing is based for air ambulance services furnished by a nonparticipating provider of air ambulance services, is the QPA. After review of the comments on the July 2021 interim final rules and October 2021 interim final rules, the Departments are finalizing parts of the July 2021 interim final rules to add a new definition and make changes to require additional information about the QPA that is provided by a plan or issuer with an initial payment or notice of denial of payment in certain cases. These disclosures are required in cases in which the recognized amount with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility, or the amount upon which cost sharing is based for air ambulance services furnished by a nonparticipating provider of air ambulance services, is the QPA. Specifically, these final rules provide a definition of the term ''downcode'' to mean the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower QPA than the service code or modifier billed by the provider, facility, or provider of air ambulance services. These final rules also specify that when a QPA is calculated based on a downcoded service code or modifier, in addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules, a plan or issuer must provide a statement that the claim was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if applicable, and a description of which modifiers were altered, added, or removed, if applicable; and the amount that would have been the QPA had the service code or modifier not been downcoded. The Departments are of the view that this additional disclosure of information about the QPA will be helpful to ensure that providers, facilities, and providers of air ambulance services receive the information regarding the QPA that may assist in their meaningful participation in open negotiation and in the Federal IDR process in all payment disputes that involve qualified items or services that have been subject to downcoding. In particular, in cases in which the plan or issuer has downcoded the billed claim, it is of particular importance that the

[47] This rulemaking builds on the July 2021 and October 2021 interim final rules described in this preamble. The interim final rules were deemed to be economically significant. The economic analyses for each of these interim final rules can be found in the **Federal Register** at 86 FR 36872 and 86 FR 55980.

[48] Pub. L. 116–260 (Dec. 27, 2020).

[49] 86 FR 36872 (July 13, 2021).

[50] 86 FR 55980 (October 7, 2021).

[51] The July 2021 and October 2021 interim final rules also include interim final regulations under 5 U.S.C. 8902(p) issued by OPM that specify how certain provisions of the No Surprises Act apply to health benefit plans offered by carriers under the Federal Employees Health Benefits Act. The rules apply to carriers in the FEHB Program with respect to contract years beginning on or after January 1, 2022.

provider, facility, or provider of air ambulance services has information regarding both the QPA (based on the downcoded service code or modifier) and the amount that would have been the QPA had the service code or modifier not been downcoded in order to ascertain what information will demonstrate that the provider's, facility's, or provider of air ambulance services' offer best represents the value of the item or service and aid the certified IDR entity in selecting an offer that best represents the value of the item or service provided.

ii. Final Rules on Payment Determinations Under the Federal IDR Process

As discussed earlier in this preamble, the October 2021 interim final rules provided that, not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must select one of the offers submitted by the plan or issuer or the provider, facility, or provider of air ambulance services to be the out-of-network rate for the qualified IDR item or service. In determining which offer to select, the October 2021 interim final rules provided that the certified IDR entity must select the offer closest to the QPA unless the certified IDR entity were to determine that additional permissible information demonstrated that the QPA is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the QPA but in opposing directions. A key goal in facilitating consistency in the Federal IDR process through the October 2021 interim final rules was to ensure a level of predictability in outcomes in the Federal IDR process. In the Departments' view, greater predictability in the Federal IDR process would encourage parties to settle disputes through open negotiation or earlier through the offer and acceptance of an adequate initial payment, which would increase efficiencies in how disputes are handled and ultimately lead to lower administrative costs associated with health care. As articulated earlier in this preamble, in light of the *Texas Medical Association* and *LifeNet* decisions, and in response to comments received on these provisions, the Departments are finalizing standards for making payment determinations that are intended to lead to greater predictability and regularity in the Federal IDR process. Accordingly, these final rules require that, in determining which offer to select during the Federal IDR process, the certified IDR entity must consider the QPA for the applicable year for the same or similar item or service. The certified IDR entity must then consider all additional information submitted by a party to determine which offer best reflects the appropriate out-of-network rate, provided that the information relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and does not include information that the certified IDR entity is prohibited from weighing in making the payment determination. In considering this additional information, the certified IDR entity should evaluate whether information that is offered is credible and should not give weight to information that is not credible. The appropriate out-of-network rate must be the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.

For non-air ambulance items and services, this information includes information related to the following factors: (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; and (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.

Under these final rules, the certified IDR entity must also consider information related to the offer provided in a response to a request from the certified IDR entity. The certified IDR entity must also consider additional information submitted by a party, provided the information relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and does not include information that the certified IDR entity is prohibited from weighing in making the payment determination under section 9816(c)(5)(D) of the Code, section 716(c)(5)(D) of ERISA, and section 2799A–1(c)(5)(D) of the PHS Act. In considering either form of information, the certified IDR entity should evaluate whether the information is credible and should not give weight to information that is not credible.

When considering the additional credible information under 26 CFR 54.9816–8(c)(4)(iii), 29 CFR 2590.716–8(c)(4)(iii), and 45 CFR 149.510(c)(4)(iii), the certified IDR entity should evaluate whether the information is already accounted for by any of the other credible information submitted by the parties. Because the certified IDR entity must consider the QPA, the certified IDR entity should always consider whether the additional credible information is already accounted for by the QPA and should avoid giving weight to information related to a factor if the certified IDR entity determines the information was already accounted for in the calculation of the QPA, to avoid weighting the same information twice. In addition, if the parties submit credible information related to more than one of the additional factors, the certified IDR entity should also consider whether the information submitted regarding those factors is already accounted for by information submitted relating to other credible information already before the certified IDR entity in relation to another factor and, if so, should not weigh the information more than once.

Regarding air ambulance services, these final rules state that the certified IDR entity must consider the QPA for the applicable year for the same or similar service and then consider all additional permissible information to determine the appropriate out-of-network rate. In considering this additional information, the certified IDR entity should evaluate whether information that is offered is credible and should not give weight to information that is not credible. For air ambulance services, this information includes information related to the following factors: (1) quality and outcomes measurements of the provider that furnished the air ambulance services; (2) the acuity of the condition of the participant or beneficiary receiving the air ambulance service, or the complexity of furnishing the service to the participant or beneficiary; (3) training, experience, and quality of the medical personnel that furnished the air ambulance services; (4) ambulance vehicle type, including the clinical capability level of the vehicle; (5) population density of the point of pick-

up; and (6) demonstrations of good faith efforts (or lack thereof) by the disputing parties to enter into network agreements with each other, as well as, if applicable, contracted rates between the parties during the previous 4 plan years.

After the certified IDR entity has reviewed and selected the offer it determines best represents the value of the qualified IDR item or service as the out-of-network rate, the certified IDR entity must explain its determination in a written decision submitted to the parties and the Departments, in a form and manner specified by the Departments. These final rules require that the certified IDR entity's written decision must include an explanation of what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted in accordance with these final rules. If the certified IDR entity relies on any additional information in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the QPA.

iii. Summary of Impacts

Plans, issuers, third-party administrators (TPAs), Federal Employees Health Benefits (FEHB) Program carriers, health care providers, facilities, providers of air ambulance services, and certified IDR entities will incur costs to comply with the requirements in these final rules. However, these final rules will help ensure that the payment determination in the Federal IDR process is a more consistent process for providers, facilities, providers of air ambulance services, plans, and issuers. These final rules will improve transparency in the Federal IDR process. This increased transparency will aid in the open negotiation process, the decision whether to initiate the Federal IDR process, and the determination of the amount a provider, facility, or provider of air ambulance services submits as an offer. Therefore, the Departments have determined the benefits of these final rules justify the costs.

This regulatory action finalizes certain provisions in the July 2021 interim final rules and the October 2021 interim final rules, including changes to remove the language vacated by the District Court in *Texas Medical Association* and *LifeNet.* This cost-benefit analysis focuses on the incremental costs of complying with the requirements that are included in these final rules. One baseline assumption for this analysis is the existence of the requirements of the July 2021 and October 2021 interim final rules, with a second baseline assumption being the use of a comparison with a hypothetical state of the world absent those interim final rules. As discussed in the analysis of the July 2021 interim final rules, the total annualized cost associated with the July 2021 interim final rules is $2,252 million, using the 7 percent discount rate.[52] As discussed in the analysis of the October 2021 interim final rules, the total annualized cost associated with the October 2021 interim final rules is $517 million, using the 7 percent discount rate.[53] The Departments consider these cost estimates to be reflected in the analytic baseline of these final rules and to form a subset of total costs of these final rules for the purposes of this cost-benefit analysis relative to the hypothetical state of the world absent the July 2021 and October 2021 interim final rules.[54] As noted in Table 1 (Accounting Statement) the Departments estimate the additional total annualized cost associated with the parts these final rules to be $5.9 million, using the 7 percent discount rate.

To avoid repeating the analysis of the July 2021 and October 2021 interim final rules, only a short summary of the benefits and costs is provided, and readers are directed to the analysis in the July 2021 and October 2021 interim final rules for more detail. Numbers in this analysis may not match numbers in the analysis for the July 2021 and October 2021 interim final rules because the estimates have been updated with the most current data. However, the methodology remains the same, except for the calculation of the burden to prepare the certified IDR entity's written decision for payment determinations, as explained later in this section. The Departments also discuss the impacts of changes made by these final rules is this section.

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this regulatory action. The Departments are unable to quantify all benefits, costs, and transfers associated with this regulatory action, but have sought, where possible, to describe these non-quantified impacts. The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these final rules.

TABLE 1—ACCOUNTING STATEMENT

Benefits:

- These final rules will increase transparency in the Federal IDR process.
- These final rules will help a provider, facility, or provider of air ambulance services ascertain what information will demonstrate that the provider's, facility's, or provider of air ambulance services' offer best represents the value of the item or service and aid the certified IDR entity in selecting an offer that best represents the value of the item or service.
- These final rules will promote more consistent payment determinations in the Federal IDR process for providers, facilities, providers of air ambulance services, plans, and issuers.
- These final rules will promote transparency with respect to the certified IDR entity's payment determination and will help to ensure that the determination of a total payment amount for a particular item or service is based on the facts and circumstances of the dispute at issue in each case.

[52] As discussed in the analysis of the July 2021 interim final rules, the total annualized cost associated with the July 2021 interim final rules is $2,177 million, using the 3 percent discount rate. The Departments note that these cost estimates have not been updated.

[53] As discussed in the analysis of the October 2021 interim final rules, the total annualized cost associated with the October 2021 interim final rules is $491 million, using the 3 percent discount rate. The Departments note that these cost estimates have not been updated.

[54] The Departments are accounting for the additional costs associated with these final rules due to parts of the July 2021 interim final rules and October 2021 interim final rules being finalized. For those parts being finalized, the *Texas Medical Association* and *LifeNet* decisions do not impact the quantified costs.

TABLE 1—ACCOUNTING STATEMENT—Continued

Costs	Estimate	Year dollar	Discount rate (%)	Period covered
Annualized Monetized ($million/Year)	$5.9	2021	7	2022–2031
	5.9	2021	3	2022–2031

Quantified Costs: The Departments estimate the total annual cost associated with these final rules to be $5.9 million, with $4.3 million annually attributable to the additional information plans and issuers will be required to provide related to the QPAs, $1.2 million annually attributable to the preparation of IDR payment determination notices by certified IDR entities for nonparticipating providers or emergency facility claims, and $0.3 million annually attributable to the preparation of IDR payment determination notices by certified IDR entities for nonparticipating air ambulance providers' claims.

Transfers: These final rules make no changes that impact the transfers as described in the July 2021 and October 2021 interim final rules.

D. Affected Entities

These final rules will affect health care providers, health care facilities, providers of air ambulance services, group health plans, issuers, TPAs, FEHB carriers, and certified IDR entities.

Based on data from 2020, CMS estimated that there were 1,477 issuers in the U.S. health insurance market, of which 1,212 served the individual market, 6 served the student health insurance market, 623 served the small group market, and 784 served the large group market.[55] Further, of the plans that filed a Form 5500 in 2019, 30,181 plans were self-insured.[56] Additionally, in the October 2021 interim final rules, the Departments previously estimated that there are 205 TPAs.[57] The Departments also estimate that there are 44 FEHB carriers. While there is a significant amount of research that demonstrates the prevalence of surprise billing, the Departments do not have data on the percentage of surprise bills covered by health insurance issuers and self-insured plans. However, given the size of health insurance issuers and the scope of their activities, the Departments assume that all health insurance issuers, TPAs, and FEHB carriers will be affected by these final rules.

In 2019, 183 million individuals had employer-sponsored coverage and 33.2 million had other private insurance, including individual market insurance.[58] The Departments do not expect that these final rules will directly affect individuals with private health coverage who visit an emergency room, visit a health care facility,[59] or are transported by an air ambulance, as these final rules contain only provisions that affect the relationships among plans and issuers; providers, facilities, and providers of air ambulance services; and certified IDR entities. However, the Departments estimate that these final rules will indirectly affect covered individuals, as the outcomes of payment disputes will have implications for premiums.

In the October 2021 interim final rules, the Departments estimated that there are 16,992 emergency and other health care facilities, including 6,090 hospitals,[60] 29,227 diagnostic and medical laboratories,[61] 270 independent freestanding emergency departments,[62] 9,280 ambulatory surgical centers,[63] and 1,352 critical access hospitals.[64] These entities will also be affected by these final rules.

In the October 2021 interim final rules, the Departments also estimated that in 2018, the current year for which data are available, there were 1,114 air ambulance bases in the United States.[65] The Departments do not have data on the number of providers of air ambulance services that submit out-of-network claims; however, given the prevalence of out-of-network billing among providers of air ambulance services, the Departments assume that all businesses in the industry will be affected by these final rules.

Furthermore, in the October 2021 interim final rules, the Departments estimated that 140,270 physicians, on average, bill on an out-of-network basis and will be affected by these final rules.[66] These final rules are also expected to affect non-physician providers who bill on an out-of-network basis. The Departments lack data on the number of non-physician providers who would be impacted.

Finally, there are currently 11 certified IDR entities that will be affected by these final rules.[67] The number of certified IDR entities may increase or decrease due to new IDR entities applying for certification or the Departments revoking certification because of noncompliance with the certification requirements or a certified IDR entity's inability to handle its caseload.

E. Benefits

These final rules will require plans and issuers to provide additional information about the QPA with an initial payment or notice of denial of payment in cases involving downcoding, without the provider, facility, or provider of air ambulance services having to ask for this information. These final rules will be helpful to the provider, facility, or provider of air ambulance services in developing an offer or submitting information if it believes that the QPA

[55] Centers for Medicare and Medicaid Services. ''Medical Loss Ratio Data and System Resources'' (2020). *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[56] Employee Benefits Security Administration. ''Group Health Plans Report.'' (July 2021). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2022-appendix-a.pdf.*

[57] Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

[58] Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2020). *https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2020.pdf.*

[59] Health care facility is defined in the July 2021 interim final rules. *See* 26 CFR 54.9816–3T; 29 CFR 2590.716–3; and 45 CFR 149.30.

[60] American Hospital Association. ''Fast Facts on U.S. Hospitals, 2021.'' (January 2021). *https://www aha.org/statistics/fast-facts-us-hospitals.*

[61] IBIS World. Definitive Healthcare. ''Diagnostic & Medical Laboratories Industry in the US—Market Research Report?'' (May 2021). *https://www ibisworld.com/industry-statistics/number-of-businesses/diagnostic-medical-laboratories-united-states/.*

[62] Emergency Medicine Network. ''2018 National Emergency Department Inventory.'' (2021). *https://www emnet-usa.org/research/studies/nedi/nedi2018/.*

[63] Definitive Healthcare. ''How Many Ambulatory Surgery Centers are in the US?'' (April 2019). *https://www.definitivehc.com/blog/how-many-ascs-are-in-the-us.*

[64] Flex Monitoring Team. ''Historical CAH Data.'' *https://www.flexmonitoring.org/*historical-cah-data-

[65] Assistant Secretary for Planning and Evaluation (ASPE) Office of Health Policy. ''Air Ambulance Use and Surprise Billing'' (September 2021). *https://aspe.hhs.gov/sites/default/files/2021-09/aspe-air-ambulance-ib-09-10-2021.pdf.*

[66] Please see the October 2021 interim final rules for more information on how these estimates were obtained.

[67] As of July 31, 2022, there are 11 certified IDR entities. Center for Medicare and Medicaid Services. ''List of Certified Independent Dispute Resolution Entities.'' *https://www cms.gov/nosurprises/Help-resolve-payment-disputes/certified-IDRE-list.*

calculated by the plan or issuer does not best represent the value of the item or service. Furthermore, the requirement to disclose this additional information will increase transparency in the Federal IDR process. This increased transparency will aid in the open negotiation process, the decision whether to initiate the Federal IDR process, and the determination of the amount a provider, facility, or provider of air ambulance services submits as an offer. Further, these final rules will help a provider, facility, or provider of air ambulance services ascertain what information will demonstrate that the provider's, facility's, or provider of air ambulance services' offer best represents the value of the item or service and aid the certified IDR entity in selecting an offer that best represents the value of the item or service.

In addition, these final rules require that certified IDR entities must consider the QPA and then must consider all additional permissible information submitted by a party to determine which offer best reflects the appropriate out-of-network rate, provided the information relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and does not include information that the certified IDR entity is prohibited from weighing in making the payment determination under section 9816(c)(5)(D) of the Code, section 716(c)(5)(D) of ERISA, and section 2799A–1(c)(5)(D) of the PHS Act. In considering this additional information, the certified IDR entity should evaluate whether information that is offered is credible and should not give weight to information that is not credible. The appropriate out-of-network rate must be the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service.

Because the certified IDR entity must consider the QPA, the certified IDR entity should always consider whether the additional credible information is already accounted for by the QPA and should not give weight to information related to a factor if the certified IDR entity determines the information was already accounted for in the calculation of the QPA, to avoid weighting the same information twice. In addition, if the parties submit credible information related to more than one of the additional factors, the certified IDR entity should also consider whether the information submitted regarding each of those factors is already accounted for by information submitted relating to other credible information already before the certified IDR entity in relation to another factor and, if so, should not weigh such information more than once. These final rules will help ensure that the payment determination in the Federal IDR process is a consistent process for providers, facilities, providers of air ambulance services, plans, and issuers.

The certified IDR entity's written decision must include an explanation of what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted in accordance with these final rules. If the certified IDR entity relies on any additional information in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount. These final rules will help ensure that certified IDR entities carefully evaluate all credible non-duplicative information. These final rules will also promote transparency with respect to the certified IDR entity's payment determination.

F. Costs

This regulatory action seeks to minimize costs to providers, facilities, providers of air ambulance services, plans, issuers, TPAs, and certified IDR entities.

i. Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities

As explained in the analysis provided in the October 2021 interim final rules, the Departments estimate that there will be approximately 17,435 claims submitted to the Federal IDR process each year.[68]

After the selected certified IDR entity has reviewed the offers, the certified IDR entity must notify the provider or facility and the plan, issuer, or FEHB carrier and the Departments of the payment determination and the reason for such determination, in a form and manner specified by the Departments.[69] The Departments estimate that the annual cost to prepare the notice of the certified IDR entity's determination is $1.2 million. For more information on this calculation, please refer to the Paperwork Reduction Act analysis, found in section V of this preamble.

In addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules, including the QPA, these final rules require that a plan or issuer must provide, if applicable, an acknowledgement if all or any portion of the claim was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and a description of any modifiers that were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded. In the July 2021 interim final rules, the Departments estimated that plans and issuers will be required to provide documents related to the QPA along with the initial payment or notice of denial of payment for approximately 5,068,512 claims annually from nonparticipating providers or facilities.[70] The Departments assume that approximately 10 percent of those claims will involve downcoding and estimate that the annual cost to prepare the required documentation and attach it to each initial payment or notice of denial of payment sent to the nonparticipating provider or facility is $4.3 million. For more information on this calculation, please refer to the Paperwork Reduction Act analysis, found in section V of this preamble.

In total, the Departments estimate that certified IDR entities, TPAs, and issuers will incur costs of approximately $5.5 million annually to provide, as applicable, payment determination notifications and the additional QPA information required under these rules.

ii. Federal IDR Process for Nonparticipating Providers of Air Ambulance Services

As explained in the October 2021 interim final rules, the Departments assume that 10 percent of out-of-network claims for air ambulance services will be submitted to the Federal IDR process,[71] which would result in nearly 5,000 annual air ambulance payment determinations via the Federal IDR process.[72]

[68] For more details, please refer to the Paperwork Reduction Act analysis, found in section V of this preamble.

[69] IDR Payment Determination Notification (section 716(c)(5)(A) of ERISA).

[70] *See* 86 FR 36872 for more information on this estimate.

[71] The Departments utilize 10 percent as an assumption to estimate the overall number of providers of air ambulance services billing out-of-network at least once in a year.

[72] The Departments estimate that of the 216.2 million individuals with employer-sponsored and other private health coverage (183 million

Continued

After the certified IDR entity has reviewed and selected the offer, the certified IDR entity must notify the provider of air ambulance services and the plan, issuer, or FEHB carrier and the Departments of the payment determination and include the written decision explaining such determination.[73] The Departments estimate that the annual cost to prepare this notice of the certified IDR entity's determination for air ambulance claims is $0.3 million. For more details, please refer to the Paperwork Reduction Act analysis, found in section V of this document.

Similar to these final rules' provisions related to the disclosure of downcoded claims for nonparticipating providers and nonparticipating emergency facilities, these final rules require that a plan or issuer must provide, if applicable, an acknowledgement if all or any portion of the claim pertaining to air ambulance services was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and a description of any modifiers that were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded. The Departments estimate that plans and issuers will be required to provide these documents for approximately 49,676 claims annually from providers of air ambulance services.[74] The Departments assume that approximately 10 percent of those claims will involve downcoding and estimate that the annual cost to prepare the required documentation and attach it to each initial payment or notice of denial of payment sent to the providers of air ambulance service is approximately $42,000. For more details, please refer to the Paperwork Reduction Act analysis, found in section V of this preamble.

In total, the Departments estimate that certified IDR entities, TPAs, and issuers will incur costs of approximately $0.4 million annually to provide payment determination notifications and the additional QPA information required under these final rules.

iii. Summary

The Departments estimate the total annual cost associated with these final rules to be $5.9 million with $4.3 million annually attributable to the additional information related to the QPAs, $1.2 million annually attributable to the certified IDR entity's payment determination for nonparticipating provider and emergency facility claims, and $0.3 million annually attributable to the certified IDR entity's payment determination notification for nonparticipating provider of air ambulance service claims.

G. Transfers

These final rules make no changes that impact the transfers as described in the July 2021 and October 2021 interim final rules.

H. Uncertainty

These final rules make no changes that impact the uncertainties as described in the July 2021 and October 2021 interim final rules.

I. Regulatory Alternatives

Section 6(a)(3)(C)(iii) of Executive Order 12866 requires an economically significant regulation, and encourages other regulations, to include an assessment of the costs and benefits of potentially effective and reasonable alternatives to the planned regulation. A discussion of the regulatory alternatives is included in this section.

As described in Section I.E. of this preamble, the District Court in *Texas Medical Association* and *LifeNet* vacated provisions in the October 2021 interim final rules addressing how certified IDR entities were to weigh the QPA and the additional factors. The Departments considered the possibility of not replacing the provisions vacated by the District Court. However, in the Departments' view, this would have resulted in uncertainty regarding the Federal IDR process, because certain aspects of the process would be governed by the October 2021 interim final rules as published in the **Federal Register**, while others would not. This approach could result in confusion on the part of the public and certified IDR entities, likely making the decisions of certified IDR entities less predictable, adding to the uncertainty and the costs of the Federal IDR process. Therefore, the Departments are of the view that it is more appropriate to make changes to the Federal IDR process for both non-air ambulance and air ambulance items and services in these final rules.

The Departments considered finalizing the additional factors other than the QPA that a certified IDR entity may consider when submitted by one of the disputing parties without addressing the possibility that these factors may already have been accounted for in the QPA. Numerous comments received on the October 2021 interim final rules highlighted that in many cases, certain factors, such as patient acuity or the complexity of furnishing the qualified IDR item or service to the participant, beneficiary, or enrollee, will already be accounted for in the calculation of the QPA. Commenters acknowledged, however, that there could be instances in which the QPA would not adequately account for the acuity of the patient or complexity of the service: for example, if the complexity of a case is an outlier such that the time or intensity of care exceeds what is typical for the service code. The Departments are of the view that, in many cases, factors that a certified IDR entity may consider other than the QPA will already be reflected in the QPA. The QPA is generally calculated to include characteristics that can affect costs, including medical specialty, geographic region, and patient acuity and case severity, all captured in different billing codes or aspects of the methodology that plans and issuers are required to follow in calculating the QPA. Therefore, weighting additional information that is already taken into account in the calculation of the QPA would be redundant and in the Departments' view, would result in increased administrative burden to the certified IDR entity, potentially resulting in the selection of an offer that does not best reflect the most appropriate value insofar as additional weight would be given to information related to a factor that is already accounted for in the QPA, effectively weighting that information twice. Under these final rules, certified IDR entities must consider the QPA and then must consider all additional information submitted by the parties. To help ensure that the Federal IDR process results in determinations that accurately reflect the fair value of a given item or service, the certified IDR entity should consider all additional information submitted by the parties but should not give weight to information if it is already accounted for by any of the other information submitted by the parties.

J. Conclusion and Summary of Economic Impacts

The Departments are of the view that these final rules will promote

individuals with employer-sponsored health coverage and 33.2 million individuals with other private coverage), there are 33.3 air transports per 100,000 individuals, of which 69 percent result in out-of-network bills. The Departments assume that 10 percent of the out-of-network bills will end up in the Federal IDR process. This is calculated as: 216,200,000 individuals × 0.000333 air transports per individual × 69% × 10%= 4,968.

[73] IDR Payment Determination Notification (section 716(c)(5)(A) of ERISA).

[74] The Departments estimate that of the 216.2 million individuals with employer-sponsored and other private health coverage, there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The number of air ambulance claims is estimated as: 216,200,000 individuals × 0.000333 air transports per individual × 69% = 49,676.

transparency, consistency, and predictability in the Federal IDR process. These final rules provide a market-based approach that will help encourage plans and issuers, and providers, facilities, and providers of air ambulance services to arrive at reasonable payment rates.

The Departments estimate that these final rules will impose incremental annual costs of approximately $5.9 million. Over 10 years, the associated costs will be approximately $44.1 million with an annualized cost of $5.9 million, using a 7 percent discount rate.[75]

V. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Departments solicited comments concerning the information collection requirements (ICRs) included in the July 2021 and October 2021 interim final rules. At the same time, the Departments also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d).

The Departments received comments that specifically addressed the paperwork burden analysis of the information collection requirements contained in the July 2021 and October 2021 interim final rules. The Departments reviewed these public comments in developing the paperwork burden analysis discussed here.

The changes made by these final rules affect the existing OMB control number, 1210–0169. A copy of the ICR for OMB Control Number 1210–0169 may be obtained by contacting the PRA addressee listed in the following sentence or at *www.RegInfo.gov.* For additional information, contact James Butikofer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; or sent to *ebsa.opr@dol.gov.*

The OMB will consider all written comments that they receive on or before September 26, 2022. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Departments, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the Departments' estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility, and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Group health plans, health insurance issuers, FEHB carriers, and certified IDR entities are responsible for ensuring compliance with these final rules. Accordingly, the Departments refer to costs incurred by plans, issuers, FEHB carriers, and certified IDR entities. However, it is expected that most self-insured group health plans will work with a TPA to meet the requirements of these final rules. The Departments recognize the potential that some of the largest self-insured plans may seek to meet the requirements of these final rules in-house and not use a TPA or other third party. In these cases, those plans will incur the estimated hour burden and cost directly.

These final rules add additional burdens to the ICR presented in the October 2021 interim final rules. The following discussion covers the changes being made to the ICR and the additional burden these changes impose, followed by a summary of the ICR. Copies of the ICR may be obtained by contacting the PRA addressee.

A. ICRs Regarding Additional Information To Be Shared With the Initial Payment or Notice of Denial of Payment (26 CFR 54.9816–6(d), 29 CFR 2590.716–6(d), and 45 CFR 149.140(d); OMB Control Number: 1210–0169)

These final rules specify that where a QPA is calculated based on a downcoded service code, in addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules, a plan or issuer must provide, if applicable, a statement that all or a portion of the claim was downcoded; an explanation of why the claim was downcoded, including a description of which service codes were altered, if any, and a description of any modifiers that were altered or added, if any; and the amount that would have been the QPA had the service codes or modifiers not been downcoded.

The Departments assume that TPAs will provide this information on behalf of self-insured plans. In addition, the Departments assume that issuers and TPAs will automate the process of preparing and providing this information in a format similar to an explanation of benefits as part of the system to calculate the QPA. The Departments estimate that a total of 1,477 issuers and 205 TPAs will incur a burden to comply with this provision.

In the July 2021 interim final rules, the Departments estimated that plans and issuers will be required to provide documents related to QPAs along with the initial payment or notice of denial of payment for approximately 5,068,512 claims annually from nonparticipating providers or facilities.[76] Additionally, the Departments estimated that plans and issuers will be required to provide these documents for approximately 49,676 claims annually from nonparticipating providers of air ambulance services.[77] In the absence of data, the Departments assume that approximately 10 percent, or 511,819, of claims from nonparticipating providers, facilities, and nonparticipating providers of air ambulance services will involve downcoding and that it will take a medical secretary 10 minutes (at an hourly rate of $50.76 [78]) to prepare the required documentation and include it with each initial payment or notice of denial of payment sent to the nonparticipating provider, facility, or provider of air ambulance services.

The Departments estimate the additional QPA information will be provided for approximately 506,851 claims from nonparticipating providers or facilities. The annual burden to prepare the required documentation and attach it to each initial payment or notice of denial of payment sent to the nonparticipating providers or facilities will be approximately 84,475 hours annually, with an associated equivalent

[75] The costs would be $51.5 million over 10-year period with an annualized cost of $5.9 million, applying a 3 percent discount rate.

[76] *See* 86 FR 36872 for more information on this estimate.

[77] The Departments estimate that of the 216.2 million individuals with employer-sponsored and other private health coverage, there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The number of air ambulance claims is estimated as: 216,200,000 individuals × 0.000333 air transports per individual × 0.69% = 49,676 claims.

[78] Internal DOL calculation based on 2021 labor cost data. For a description of DOL's methodology for calculating wage rates, see *https://www dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf*

cost of $4.3 million.[79] The Departments estimate that the additional QPA information will be provided for approximately 4,968 claims from providers of air ambulance services. The annual burden to prepare the required documentation and attach it to each initial payment or notice of denial of payment sent to providers of air ambulance services will be approximately 828 hours annually, with an associated equivalent cost of $42,029.[80] Thus, the total estimated burden to provide the additional QPA information with initial payments or notices of denial of payment sent to the nonparticipating providers, facilities, and providers of air ambulance services, for all issuers and TPAs, will be approximately 85,303 hours annually, with an associated equivalent cost of approximately $4.3 million.[81] As shown in Table 2, the Departments share jurisdiction, and it is estimated that 50 percent of the burden will be accounted for by HHS, 25 percent of the burden will be accounted for by DOL, and 25 percent will be accounted for by Department of the Treasury. Thus, HHS will account for approximately 42,652 hours with an equivalent cost of approximately $2,164,990. DOL and the Department of the Treasury will each account for approximately 21,326 hours with an equivalent cost of approximately $1,082,495.

TABLE 2—SUMMARY ANNUAL COST AND BURDEN REGARDING INFORMATION TO BE SHARED ABOUT QPA STARTING IN 2022

Department	Estimated number of responses	Total annual burden (hours)	Estimated dollar value of labor hours
HHS	255,910	42,652	$2,164,990
DOL	127,955	21,326	1,082,495
Treasury	127,955	21,326	1,082,495

B. ICRs Regarding the Certified IDR Entity's Payment Determination Written Decision in the Federal IDR Process for Nonparticipating Providers or Nonparticipating Emergency Facilities (26 CFR 54.9816–8T, 26 CFR 54.9816–8, 29 CFR 2590.716–8, and 45 CFR 149.510; OMB Control Number: 1210–0169)

The Departments estimate that 17,435 claims will be submitted as part of the Federal IDR process each year.[82] After the certified IDR entity has reviewed the offers and credible information submitted by the parties and selected an offer, the certified IDR entity must notify the provider, facility, or provider of air ambulance services and the plan, issuer, or FEHB carrier and the Departments of the payment determination and the reason for such determination, in a form and manner specified by the Departments.[83] The certified IDR entity's written decision must include an explanation of the additional non-prohibited information that the certified IDR entity determined demonstrated that the offer selected is the out-of-network rate that best represents the value of the qualified IDR item or service, including the weight given to the QPA and any additional credible information submitted in accordance with these final rules. If the certified IDR entity relies on any additional information in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

The Departments estimate that, on average, it will take a physician and medical billing specialist 0.5 hours to prepare the notice at a composite hourly wage rate of $136.81.[84] The burden for each certified IDR entity will be 0.5 hours, with an equivalent cost of approximately $69.24. Thus, the total cost burden for all certified IDR entities to prepare this notice for Federal IDR claims will be $1.2 million.[85]

The total annual cost burden for certified IDR entities to provide the payment determination notices regarding Federal IDR claims will be $1,192,641. As shown in Table 3, the Departments and OPM share jurisdiction, and it is estimated that 45 percent of the burden will be accounted for by HHS, 25 percent will be accounted for by DOL, 25 percent of the burden will be accounted for by the Department of the Treasury, and 5 percent will be accounted for by OPM. Thus, HHS will account for a cost burden of $536,689. DOL and the Department of the Treasury will each account for a cost burden of $298,160. OPM will account for a cost burden of $59,632.

[79] This is calculated as: (5,068,512 documents for nonparticipating providers or facilities) × (10%) × (10 minutes) = 84,475 hours. 84,475 hours × $50.76 = $4,287,951.

[80] This is calculated as: (49,676 documents for nonparticipating providers of air ambulance services) × (10%) × (10 minutes) = 828 hours. 828 hours × $50.76 = $42,029.

[81] This is calculated as: (5,068,512 documents for nonparticipating providers or facilities + 49,676 documents for nonparticipating providers of air ambulance services) × (10%) × (10 minutes) = 85,303 hours. 85,303 hours × $50.76 = $4,329,980.

[82] In 2020, 10.7 million individuals had employer-sponsored coverage and 1.7 million individuals had other private coverage in New York State, while 183 million individuals had employer-sponsored coverage and 33.2 million individuals had other private coverage nationally. The Departments estimate that New York accounts for 5.7 percent of the private insurance market ((10.7 + 1.7)/(183 + 33.2) = 5.7 percent). (*See* Employee Benefits Security Administration. ''Health Insurance Coverage Bulletin.'' (March 2020).) In 2018, New York State had 1,014 IDR decisions, up from 650 in 2017 and 396 in 2016. (*See* Adler, Loren. ''Experience with New York's Arbitration Process for Surprise Out-of-Network Bills.'' U.S.C.-Brookings Schaeffer on Health Policy. (October 2019).) For purposes of this analysis, the Departments assume that, going forward, New York State will continue to see 1,000 IDR cases each year and that the number of Federal IDR cases will be proportional to that in New York State by share of covered individuals in the private health coverage market. The number of claims in the Federal IDR process is calculated in the following manner: 1,000/0.057= 17,435.

[83] IDR Payment Determination Notification (section 716(c)(5)(A) of ERISA).

[84] The Departments use a composite wage rate because different professionals will review different types of claims and groups of individuals. The wage rate of a physician is $192.37, and the wage rate of a medical billing specialist is $109.03. (Internal DOL calculation based on 2021 labor cost data. For a description of DOL's methodology for calculating wage rates, see *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.*) The composite wage rate is estimated in the following manner: ($192.37 × (⅓) + $109.03 × (⅔) = $136.81).

[85] 17,453 claims × 0.5 hours × $136.81 as the composite wage rate for a physician and medical billing specialist = $1,192,641.

TABLE 3—SUMMARY ANNUAL COST AND BURDEN STARTING IN 2022 REGARDING CERTIFIED IDR ENTITY'S PAYMENT DETERMINATION WRITTEN DECISION IN THE FEDERAL IDR PROCESS FOR NONPARTICIPATING PROVIDERS OR NONPARTICIPATING EMERGENCY FACILITIES CLAIMS

Department	
HHS	$536,689
DOL	298,160
Treasury	298,160
OPM	59,632

C. ICRs Regarding the Certified IDR Entity's Payment Determination Written Decision in the Federal IDR Process for Nonparticipating Providers of Air Ambulance Services (26 CFR 54.9817–2T, 26 CFR 54.9817–2, 29 CFR 2590.717–2, and 45 CFR 149.520; OMB Control Number: 1210–0169)

The Departments estimate there will be 4,968 claims for air ambulance services submitted to the Federal IDR process each year.[86] After the certified IDR entity has reviewed the offers and any submitted credible information, and selected an offer, the certified IDR entity must notify the provider of air ambulance services and the plan, issuer, or FEHB carrier and the Departments of the payment determination and include the written decision explaining such determination.[87] The certified IDR entity's written decision must include an explanation of what information that the certified IDR entity determined demonstrated that the offer selected is the out-of-network rate that best represents the value of the qualified IDR service. This explanation must include the weight given to the QPA and any additional non-prohibited, credible information submitted in accordance with these final rules. If the certified IDR entity relies on any additional information in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

[86] The Departments estimate that of the 183 million individuals with employment-related health insurance and 33.2 million individuals with other private coverage, there are 33.3 air transports per 100,000 individuals, of which 69 percent result in an out-of-network bill. The Departments assume that 10 percent of the out-of-network bills will end up in the Federal IDR process. The number of air ambulance service claims is calculated in the following manner: (183,000,000 individuals + 33,200,000 individuals) × 0.000333 air transports per individual × 69% × 10%= 4,968 claims.

[87] IDR Payment Determination Notification (section 716(c)(5)(A) of ERISA).

The Departments estimate that, on average, it will take a physician and medical billing specialist working for the certified IDR entity 0.5 hour to prepare the notice of the certified IDR entity's determination at a composite hourly wage rate of $136.81.[88] The burden for each certified IDR entity will be 0.5 hours, with an equivalent cost of approximately $69.24. Thus, the total cost burden for certified IDR entities to provide this notice for air ambulance claims will be $0.3 million.[89]

The total annual cost burden for the certified IDR entities to provide the payment determination notices regarding air ambulance claims will be $339,836. As shown in Table 4, the Departments and OPM share jurisdiction, and it is estimated that 45 percent of the burden will be accounted for by HHS, 25 percent will be accounted for by DOL, 25 percent of the burden will be accounted for by the Department of the Treasury, and 5 percent will be accounted for by OPM. Thus, HHS will account for a cost burden of $152,926. DOL and the Department of the Treasury will each account for a cost burden of $84,959. OPM will account for a cost burden of $16,992.

TABLE 4—SUMMARY ANNUAL COST AND BURDEN STARTING IN 2022 REGARDING CERTIFIED IDR ENTITY'S PAYMENT DETERMINATION WRITTEN DECISION IN THE FEDERAL IDR PROCESS FOR AIR AMBULANCE CLAIMS

Department	Estimated number of responses	Total estimated cost
HHS	2,235	$152,926
DOL	1,242	84,959
Treasury	1,242	84,959
OPM	248	16,992

Summary

The total annual cost burden for certified IDR entities to provide payment determination notices regarding non-air ambulance and air ambulance claims will be $1,532,477. As shown in Table 5, HHS will account for a cost burden of approximately $689,615. DOL and the Department of the Treasury will each account for a cost burden of approximately $383,119. OPM will account for a cost burden of approximately $76,624.

TABLE 5—SUMMARY ANNUAL COST AND BURDEN STARTING IN 2022 REGARDING CERTIFIED IDR ENTITY'S PAYMENT DETERMINATION WRITTEN DECISION IN THE FEDERAL IDR PROCESS FOR NON-AIR AMBULANCE AND AIR AMBULANCE CLAIMS

Department	Estimated number of responses	Total estimated cost
HHS	10,145	$689,615
DOL	5,636	383,119
Treasury	5,636	383,119
OPM	1,127	76,624

These paperwork burden estimates are summarized as follows:

Agency: Employee Benefits Security Administration, Department of Labor.

Type of Review: Revision of existing collection.

Title: Requirements Related to Surprise Billing: Payment Determination.

OMB Control Number: 1210–0169.

Affected Public: Private Sector—Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 22,828

Estimated Number of Annual Responses: 163,542

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 89,521

Estimated Total Annual Burden Cost: $555,427

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[90] imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (APA) and are not likely to have a significant economic impact on a substantial number of small entities. Unless the head of an agency determines that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 604[91] of the RFA requires the agency to present a final regulatory flexibility analysis of these final rules.

The Departments certify that these final rules would not have a significant

[88] The Departments use a composite wage rate because different professionals will review different types of claims and groups of individuals. The wage rate of a physician is $192.37, and the wage rate of a medical billing specialist is $109.03. (Internal DOL calculation based on 2021 labor cost data. For a description of DOL's methodology for calculating wage rates, see *https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf*.) The composite wage rate is estimated in the following manner: ($192.37 × (⅓) + $109.03 × (⅔) = $136.81).

[89] 4,968 air ambulance claims × 0.5 hours × $136.81 as the composite wage rate for a physician and medical billing specialist = $339,836.

[90] 5 U.S.C. 601 *et seq.* (1980).

[91] 5 U.S.C. 604 (1980).

impact on a substantial number of small entities during the first year. The Departments have prepared a justification for this determination below.

A. Affected Small Entities

The Small Business Administration (SBA), pursuant to the Small Business Act,[92] defines small businesses and issues size standards by industry. These final rules will affect all health insurance issuers, TPAs, and certified IDR entities.

For purposes of analysis under the RFA, the Departments consider an employee benefit plan with fewer than 100 participants to be a small entity.[93] The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3) of ERISA, the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), DOL has previously issued simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, which cover fewer than 100 participants and satisfy certain requirements. See 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10. While some large employers have small plans, small plans are maintained generally by small employers. Thus, the Departments are of the view that assessing the impact of these final rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business based on size standards promulgated by the SBA [94] pursuant to the Small Business Act.[95]

As discussed in the regulatory impact analysis, these final rules will affect health insurance issuers and TPAs. In 2020, there were 205 TPAs [96] and 1,477 issuers in the U.S. health insurance market.[97] Most TPAs would be classified under the North American Industry Classification System (NAICS) code 524292 (Third Party Administration of Insurance and Pension Funds). According to SBA size standards,[98] entities with average annual receipts of $40 million or less are considered small entities. By this standard, the Departments estimate that 63.5 percent of TPAs (130 TPAs) are small under the SBA's size standards.[99] Most health insurance issuers would be classified under the NAICS code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[100] entities with average annual receipts of $41.5 million or less are considered small entities. By this standard, the Departments estimate that 8.5 percent of issuers (125 issuers), are small under the SBA's size standards.[101]

This estimate may overstate the actual number of small health insurance issuers that may be affected. The Departments expect that few insurance issuers underwriting comprehensive health insurance coverage fall below these size thresholds. Based on data from medical loss ratio (MLR) annual report [102] submissions for the 2020 MLR reporting year, approximately 78 out of 481 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less. This estimate may overstate the actual number of small health insurance issuers that may be affected, since over 72 percent of these small issuers belong to larger holding groups, and many, if not all, of these small issuers are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million. However, to produce a conservative estimate, for the purposes of this analysis, the Departments assume 8.5 percent, (125 issuers) are considered small entities.

These final rules will also affect health care providers because the Departments assume that the cost of preparing and delivering the notice of the certified IDR entity's determination is included in the certified IDR entity fees paid by providers, facilities, providers of air ambulance services, plans, issuers, and FEHB carriers. The Departments estimate that 140,270 physicians, on average, bill on an out-of-network basis. The number of small physicians is estimated based on the SBA's size standards. The size standard applied for providers is NAICS 62111 (Offices of Physicians), for which a business with less than $14 million in receipts is considered to be small. By this standard, the Departments estimate that 45.8 percent (64,232 physicians) are considered small under the SBA's size standards.[103] These final rules are also expected to affect non-physician providers who bill on an out-of-network basis. The Departments lack data on the number of non-physician providers who would be impacted.

The Departments do not have the same level of data for the air ambulance sub-sector. In 2020, the total revenue of providers of air ambulance services is estimated to be $4.2 billion with 1,114 air ambulance bases.[104] This results in an industry average of $3.8 million per air ambulance base. Accordingly, the Departments are of the view that most providers of air ambulance services are likely to be small entities.

B. Impact of the Final Rules

In addition to the information already required to be provided with an initial payment or notice of denial of payment under the July 2021 interim final rules, including the QPA, these final rules require that a plan or issuer must provide, if applicable, an acknowledgement if all or any portion of the claim was downcoded; an explanation of why the claim was

[92] 15 U.S.C. 631 *et seq.*

[93] The Departments consulted with the Small Business Administration Office of Advocacy in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c) in a memo dated June 4, 2020.

[94] 13 CFR 121.201 (2011).

[95] 15 U.S.C. 631 *et seq.* (2011).

[96] Non-issuer TPAs based on data derived from the 2016 Benefit Year reinsurance program contributions.

[97] Centers for Medicare and Medicaid Services. ''Medical Loss Ratio Data and System Resources'' (2020). *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.*

[98] Available at *https://www.sba.gov/document/support—table-size-standards.*

[99] Based on data from the NAICS Association for NAICS code 524292, the Departments estimate the percent of businesses within the industry of Third Party Administration of Insurance and Pension Funds with less than $40 million in annual sales. (See NAICS Association. ''Market Analysis Profile: NAICS Code & Annual Sales.'' *https://www.naics com/business-lists/counts-by-naics-code/.*)

[100] Available at *https://www.sba.gov/document/support—table-size-standards.*

[101] Based on data from the NAICS Association for NAICS code 524114, the Departments estimate the percent of businesses within the industry of Direct Health and Medical Insurer Carriers with less than $41.5 million in annual sales. (*See* NAICS Association. ''Market Analysis Profile: NAICS Code & Annual Sales.'' *https://www.naics com/business-lists/counts-by-naics-code/.*)

[102] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

[103] Based on data from the NAICS Association for NAICS code 62111, the Departments estimate the percent of businesses within the industry of Offices of Physicians with less than $14 million in annual sales. (*See* NAICS Association. ''Market Analysis Profile: NAICS Code & Annual Sales.'' *https://www.naics.com/business-lists/counts-by-naics-code/.*)

[104] ASPE Office of Health Policy. ''Air Ambulance Use and Surprise Billing'' (September 2021). *https://aspe.hhs.gov/sites/default/files/2021-09/aspe-air-ambulance-ib-09-10-2021.pdf.* U.S. Small Business Administration. ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes.'' *https://www.naics.com/business-lists/counts-by-naics-code/. https://www.sba.gov/sites/default/files/2022-05/Table%20of%20Size%20Standards_Effective%20May%202%202022_Final.pdf.*

downcoded, including a description of which service codes were altered, if any, and a description of any modifiers that were altered, added, or removed, if any; and the amount that would have been the QPA had the service code or modifier not been downcoded. The total annual burden for all issuers and TPAs for providing the additional information related to the QPA is estimated to be 85,303 hours with an equivalent cost of approximately $4.3 million. For more details, please refer to the Paperwork Reduction Act analysis, found in section VI of this preamble.

In addition, after the certified IDR entity has reviewed the offers and selected an offer, the certified IDR entity must explain its determination in a written decision submitted to the parties and the Departments, in a form and manner specified by the Departments. The certified IDR entity's written decision must include an explanation of what information the certified IDR entity determined demonstrated that the offer selected is the out-of-network rate that best represents the value of the qualified IDR item or service. This explanation must include the weight given to the QPA and any additional non-prohibited, credible information submitted in accordance with these final rules. If the certified IDR entity relies on any additional information in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount. The total estimated annual cost burden for certified IDR entities to provide payment determination notices regarding non-air ambulance Federal IDR claims is estimated to be $1.2 million and the total estimated annual cost burden for certified IDR entities to provide payment determination notices regarding air ambulance Federal IDR claims is estimated to be $0.3 million. The Departments assume for this calculation that half of the cost will fall on the providers, providers of air ambulance services, and facilities and the remaining half will fall on plans, issuers, and FEHB carriers. For more details, please refer to the Paperwork Reduction Act analysis, found in section V of this preamble.

To estimate the proportion of the total costs that would fall onto small entities, the Departments assume that the proportion of costs is proportional to the industry receipts. The Departments are of the view that this assumption is reasonable because the number of providers, facilities, and providers of air ambulance services that receive initial and additional information about the QPA is likely to be proportional to the amount of business in which the entity is involved. Applying data from the Census Bureau of receipts by size for each industry, the Departments estimate that small issuers will incur 0.2 percent of the total costs incurred by all issuers and small providers will incur 37 percent of the total cost by all providers.[105]

Accordingly, the Departments estimate that small issuers and TPAs will incur an annual cost of $4,330 associated with disclosing additional information about the QPA.[106] For each small issuer and TPA, this results in an estimated annual cost of $16.98.[107]

For the payment determination notice regarding disputes involving non-air ambulance claims, the Departments estimate that the total annual cost for all small issuers will be $1,193 and the total annual cost for small providers will be $219,446.[108] This results in a per-entity annual cost of $9.54 for small issuers and a per-entity annual cost of $3.42 for small providers that are not providers of air ambulance services.[109]

For the payment determination notice regarding a dispute involving air ambulance claims, the Departments estimate that the total annual cost for small issuers will be $344 and the total annual cost for all small providers of air ambulance services will be $62,530.[110] This results in a per-entity annual cost of $2.72 for small issuers and a per-entity annual cost of $56.13 for small providers of air ambulance services.[111]

The number of impacted small health plans is not a significant number of plans compared to the total universe of 1.9 million small health plans. Assuming that 17,435 non-air ambulance claims and 4,968 air ambulance claims are submitted to the Federal IDR process each year, only one percent of small health plans will be impacted.[112] The number of impacted plans and issuers may be even smaller, if some plans and issuers have multiple disputes that are batched in the Federal IDR process. By batching qualified IDR items and services, there may be a reduction in the per-service cost of the Federal IDR process, and potentially the aggregate administrative costs, because the Federal IDR process is likely to exhibit at least some economies of scale.[113]

VII. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed agency rule, or a finalization of such a proposal, that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector.[114] In 2022, that threshold is approximately $165 million. For purposes of the UMRA, these final rules do not include any Federal mandate that the Departments expect to result in such expenditures by State, local, or tribal governments.

VIII. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism and requires Federal agencies to adhere to specific criteria when formulating and implementing policies that have ''substantial direct effects'' on the States, the relationship between the National Government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to these final rules.

In the Departments' view, these final rules have federalism implications

[105] Census Bureau. ''2017 SUSB Annual Data Tables by Establishment Industry, Data by Enterprise Receipt Size.'' (May 2021). *https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html.*

[106] The annual cost is estimated as: $4,329,980 × 0.5 × 0.2% = $4,330.

[107] The cost is estimated as: $4,330/(125 Issuers + 130 TPAs) = $16.98.

[108] The annual cost for issuers is estimated as: $1,192,641 × 0.5 × 0.2% = $1,193. The annual cost for small physicians is estimated as: $1,192,641 × 0.5 × 36.8% = $219,446.

[109] The annual per-claim cost for issuers is estimated as: $1,193/125 Issuers = $9.54. The annual per-claim cost for small physicians is estimated as: $219,446/64,232 small physicians = $3.42.

[110] The annual cost for issuers is estimated as: $339,836 × 0.5 × 0.2% = $340. The annual cost for small providers of air ambulance services is estimated as: $339,836 × 0.5 × 36.8% = $62,530.

[111] The annual per-claim cost for issuers is estimated as: $340/125 Issuers = $2.72. The annual per-claim cost for small providers of air ambulance services is estimated as: $62,530/1,114 providers of air ambulance services = $56.13.

[112] (17,435 claims + 4,968 air ambulance claims)/1,927,786 ERISA health plans = 1% (*Source:* 2020 Medical Expenditure Panel Survey-Insurance Component).

[113] Matthew Fiedler, Loren Adler, and Benedic Ippolito. ''Recommendations for Implementing the No Surprises Act.'' U.S.C.-Brookings Schaeffer on Health Policy. (March 2021). *https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2021/03/16/recommendations-for-implementing-the-no-surprises-act/.*

[114] 2 U.S.C. 1501 *et seq.* (1995).

because they have direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among various levels of government. State and local government providers, facilities, and health plans may be subject to the Federal IDR process or an All-Payer Model Agreement or a specified State law. Additionally, the No Surprises Act authorizes States to enforce the new requirements, including those related to balance billing, with respect to issuers, providers, facilities, and providers of air ambulance services, with HHS enforcing only in cases in which the State has notified HHS that the State does not have the authority to enforce or is otherwise not enforcing, or HHS has made a determination that a State has failed to substantially enforce the requirements. However, in the Departments' view, the federalism implications of these final rules are substantially mitigated because the Departments expect that some States will have their own process for determining the total amount payable under a plan or coverage. Where a State does not have an applicable All-Payer Model Agreement, but does have such a specified State law, the State law, rather than the Federal IDR process, will apply. The Departments anticipate that some States with their own IDR processes or other mechanism for determining the out-of-network rate may want to change their laws or adopt new laws in response to these final rules. The Departments anticipate that these States will incur a small incremental cost when making changes to their laws.

In general, section 514 of ERISA preempts state laws to the extent that they relate to any private covered employee benefit plan, including covered group health plans, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that requirements of Part 7 of ERISA and title XXVII of the PHS Act (including those of the No Surprises Act) are not to be ''construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement'' of a Federal standard. The conference report accompanying the Health Insurance Portability and Accountability Act of 1996 (HIPAA) indicates that this is intended to be the ''narrowest'' preemption of State laws.[115] Additionally, the No Surprises Act requires that when a State law determines the total amount payable under such a plan, coverage, or issuer for emergency services or to nonparticipating providers related to patient visits to participating facilities for nonemergency services, the State law will apply, rather than the Federal IDR process specified in these final rules.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy-making discretion of the States, the Departments engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the NAIC and consulting with State insurance officials on a state-by-state basis. In addition, the Departments consulted with the NAIC, as required by the No Surprises Act, to establish the geographic regions to be used in the methodology for calculating the QPA as detailed in the July 2021 interim final rules.

In developing these final rules, the Departments attempted to balance the States' interests in regulating health insurance issuers, providers, and facilities with the need to ensure at least the minimum Federal consumer protections in every State. By doing so, the Departments complied with the requirements of Executive Order 13132.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 149

Balance billing, Health care, Health insurance, Reporting and recordkeeping requirements, Surprise billing, State regulation of health insurance, Transparency in coverage.

[115] See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

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Internal Revenue Service

Adoption of the Amendments to the Regulations

Accordingly, the Treasury Department and the IRS adopts as final the temporary regulations adding 26 CFR 54.9816–6T and 54.9817–2T, published at 86 FR 36872 (July 13, 2021), and 26 CFR 54.9816–8T, published at 86 FR 55980 (October 7, 2021), with the following changes to 26 CFR part 54:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

* * * * *

■ 2. Section 54.9816–6 is added to read as follows:

§ 54.9816–6 Methodology for calculating qualifying payment amount.

(a) For further guidance see § 54.9816–6T(a) introductory text through (a)(17).

(1)–(17) [Reserved]

(18) *Downcode* means the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower qualifying payment amount than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

(b)–(c) For further guidance see § 54.9816–6T(b) and (c).

(d) For further guidance see § 54.9816–6T(d) introductory text through (d)(1)(i).

(1) [Reserved]

(i) [Reserved]

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider,

facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded.

(iii)–(v) For further guidance see § 54.9816–6T(d)(1)(iii) through (v).

(2) For further guidance see § 54.9816–6T(d)(2).

(e)–(f) For further guidance see § 54.9816–6T(e) and (f).

(g) *Applicability date.* The provisions of this section are applicable for plan years beginning on or after January 1, 2022, except that paragraph (a)(18) of this section regarding the definition of the term ''downcode'' and paragraph (d)(1)(ii) of this section regarding additional information that must be provided if the qualifying payment amount is based on a downcoded service code or modifier are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

■ 3. Section 54.9816–6T is amended by:

■ a. Adding paragraph (a)(18);

■ b. Redesignating paragraphs (d)(1)(ii) through and (iv) as paragraphs (d)(1)(iii) through (v), respectively; and

■ c. Adding a new paragraph (d)(1)(ii).

The additions read as follows:

§ 54.9816–6T Methodology for calculating qualifying payment amount (temporary).

(a) * * *

(18) For further guidance see § 54.9816–6(a)(18).

* * * * *

(d) * * *

(1) * * *

(ii) For further guidance see § 54.9816–6(d)(1)(ii);

* * * * *

■ 4. Section 54.9816–8 is added to read as follows:

§ 54.9816–8 Independent dispute resolution process.

(a)–(b) For further guidance see § 54.9816–8T(a) and (b).

(c) For further guidance see § 54.9816–8T(c) introductory text through (c)(3).

(1)–(3) [Reserved]

(4) For further guidance see § 54.9816–8T(c)(4) introductory text through (c)(4)(ii) introductory text.

(i) [Reserved]

(ii) [Reserved]

(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under § 54.9816–8T(c)(4)(i), weighing only the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to § 54.9816–8T(c)(4)(i)). The certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

(B) For further guidance see § 54.9816–8T(c)(4)(ii)(B).

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*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 or beneficiary receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*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.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under § 54.9816–8T(c)(4)(i)(A)(*2*) that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in § 54.9816–8T(c)(4)(v).

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in § 54.9816–8T(c)(4)(v).

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1*—(*1*) *Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by

either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the

payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 54.9816–6(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 54.9816–6(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

(v) For further guidance see § 54.9816–8T(c)(4)(v) through (c)(4)(vi)(A).

(vi) [Reserved]

(A) [Reserved]

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

(vii)–(ix) For further guidance see § 54.9816–8T(c)(4)(vii) through (ix).

(d)–(e) For further guidance see § 54.9816–8T(d) through (e).

(f) For further guidance see § 54.9816–8T(f) introductory text through (f)(1)(iv).

(1) [Reserved]

(i)–(iv) [Reserved]

(v) For further guidance see § 54.9816–8T(f)(1)(v) introductory text through (f)(1)(v)(E).

(A)–(E) [Reserved]

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraphs (c)(4)(iii)(B) through (D) of this section.

(G)–(I) For further guidance see § 54.9816–8T(f)(1)(v)(G) through (I).

(vi) For further guidance see § 54.9816–8T(f)(1)(vi).

(2) [Reserved]

(g) For further guidance see § 54.9816–8T(g).

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

■ 5. Section 54.9816–8T is amended by:
■ a. Removing paragraph (a)(2)(viii);
■ b. Redesignating paragraphs (a)(2)(ix) through (xiii) as paragraphs (a)(2)(viii) through (xii), respectively; and
■ c. Revising paragraphs (c)(4)(ii)(A), (c)(4)(iii) and (iv), (c)(4)(vi)(B), (f)(1)(v)(F), and (h).

The revisions read as follows:

§ 54.9816–8T Independent dispute resolution process (temporary).

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(A) For further guidance see § 54.9816–8(c)(4)(ii)(A).

* * * * *

(iii) For further guidance see § 54.9816–8(c)(4)(iii).

(iv) For further guidance see § 54.9816–8(c)(4)(iv).

* * * * *

(vi) * * *

(B) For further guidance see § 54.9816–8(c)(4)(vi)(B).

* * * * *

(f) * * *

(1) * * *

(v) * * *

(F) For further guidance see § 54.9816–8(f)(1)(v)(F);

* * * * *

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of

this section are applicable beginning on October 7, 2021; and paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

■ 6. Section 54.9817–2 is added to read as follows:

§ 54.9817–2 Independent dispute resolution process for air ambulance services

(a) For further guidance see § 54.9817–2T(a).

(b) For further guidance see § 54.9817–2T(b) introductory text.

(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section and § 54.9817–2T(b)(2) and (4), in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of §§ 54.9816–8T and 54.9816–8, except that references in §§ 54.9816–8T and 54.9816–8 to the additional circumstances in § 54.9816–8(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section and § 54.9817–2T(b)(2).

(2) *Considerations for air ambulance services.* In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

(i)–(vi) For further guidance see § 54.9817–2T(b)(2)(i) through (vi).

(3) *Weighing considerations.* In weighing the considerations described in paragraph (b)(2) of this section and § 54.9817–2T(b)(2), the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under § 54.9816–8(c)(4)(iii)(A) or other credible information under § 54.9816–8(c)(4)(iii)(B) through (D), except that the additional circumstances in § 54.9816–8(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section and § 54.9817–2T(b)(2).

(4) For further guidance see § 54.9817–2T(b)(4) introductory text through (b)(4)(iii).

(i)–(iii) [Reserved]

(iv) For further guidance see § 54.9817–2T(b)(4)(iv) introductory text through (b)(4)(iv)(E).

(A)–(E) [Reserved]

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section and § 54.9816–8(c)(4)(iii)(C) and (D).

(G)–(I) For further guidance see § 54.9817–2T(b)(4)(iv)(G) through (I).

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

■ 7. Section 54.9817–2T is amended by:

■ a. Revising paragraphs (b)(1) and (2);

■ b. Redesignating paragraph (b)(3) as paragraph (b)(4);

■ c. Adding a new paragraph (b)(3); and

■ d. Revising newly redesignated paragraph (b)(4)(iv)(F) and paragraph (c).

The revisions and addition read as follows:

§ 54.9817–2T Independent dispute resolution process for air ambulance services (temporary).

* * * * *

(b) * * *

(1) For further guidance see § 54.9817–2(b)(1).

(2) For further guidance see § 54.9817–2(b)(2).

(3) For further guidance see § 54.9817–2(b)(3).

(4) * * *

(iv) * * *

(F) For further guidance see § 54.9817–2(b)(4)(iv)(F);

* * * * *

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim rules adding 29 CFR 2590.716–6, published at 86 FR 36872 (July 13, 2021), and 29 CFR 2590.716–8 and 2590.717–2, published at 86 FR 55980 (October 7, 2021), with the following changes:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 8. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a–n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L.104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Pub. L. 116–260 134 Stat. 1182; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 9. Section 2590.716–6 is amended by:

■ a. Adding paragraph (a)(18);

■ b. Redesignating paragraphs (d)(1)(ii) through (iv) as paragraphs (d)(1)(iii) through (v), respectively;

■ c. Adding a new paragraph (d)(1)(ii); and

■ d. Revising paragraph (f).

The revisions and additions read as follows:

§ 2590.716–6 Methodology for calculating qualifying payment amount.

(a) * * *

(18) *Downcode* means the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower qualifying payment amount than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

* * * * *

(d) * * *

(1) * * *

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a

description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded;

* * * * *

(f) *Applicability date.* The provisions of this section are applicable for plan years beginning on or after January 1, 2022, except that paragraph (a)(18) of this section regarding the definition of the term ''downcode'' and paragraph (d)(1)(ii) of this section regarding additional information that must be provided if the qualifying payment amount is based on a downcoded service code or modifier are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

■ 10. Section 2590.716–8 is amended by:

■ a. Removing paragraph (a)(2)(viii);

■ b. Redesignating paragraphs (a)(2)(ix) through (xiii) as paragraphs (a)(2)(viii) through (xii), respectively; and

■ c. Revising paragraphs (c)(4)(ii)(A), (c)(4)(iii) and (iv), (c)(4)(vi)(B), (f)(1)(v)(F), and (h).

The revisions read as follows:

§ 2590.716–8 Independent dispute resolution process.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(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, weighing only 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 that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

* * * * *

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*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 or beneficiary receiving the qualified IDR item or service, or the complexity of furnishing the qualified IDR item or service to the participant or beneficiary.

(*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.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1*—(*1*) *Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the

additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in

relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5—(1) Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 2590.716–6(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 2590.716–6(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

* * * * *

(vi) * * *

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

* * * * *

(f) * * *

(1) * * *

(v) * * *

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraphs (c)(4)(iii)(B) through (D) of this section;

* * * * *

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021; and paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

■ 11. Section 2590.717–2 is amended by:

■ a. Revising paragraphs (b)(1) and (b)(2) introductory text;

■ b. Redesignating paragraph (b)(3) as paragraph (b)(4);

■ c. Adding a new paragraph (b)(3); and

■ d. Revising newly redesignated paragraph (b)(4)(iv)(F) and paragraph (c).

The addition and revisions read as follows:

§ 2590.717–2 Independent dispute resolution process for air ambulance services.

* * * * *

(b) * * *

(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 2590.716–8, except that references in § 2590.716–8 to the additional circumstances in § 2590.716–8(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Considerations for air ambulance services.* In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

* * * * *

(3) *Weighing considerations.* In weighing the considerations described in paragraph (b)(2) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under § 2590.716–8(c)(4)(iii)(A) or other credible information under § 2590.716–8(c)(4)(iii)(B) through (D), except that the additional circumstances in § 2590.716–8(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(4) * * *

(iv) * * *

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section and § 2590.716–8(c)(4)(iii)(C) and (D);

* * * * *

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years beginning on or after January 1, 2022.

Department of Health and Human Services

45 CFR Subtitle A, Subchapter B

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim rules adding 45 CFR 149.140, published at 86 FR 36872 (July 13, 2021), and 45 CFR 149.510 and 149.520, published at 86 FR 55980 (October 7, 2021), with the following changes to 45 CFR part 149:

PART 149—SURPRISE BILLING AND TRANSPARENCY REQUIREMENTS

■ 12. The authority citation for part 149 continues to read as follows:

Authority: 42 U.S.C. 300gg–92 and 300gg–111 through 300gg–139, as amended.

■ 13. Section 149.140 is amended by:
■ a. Adding paragraph (a)(18);
■ b. Redesignating paragraphs (d)(1)(ii) through (iv) as paragraphs (d)(1)(iii) through (v), respectively;
■ c. Adding a new paragraph (d)(1)(ii); and
■ d. Revising paragraph (g).

The revisions and additions read as follows:

§ 149.140 Methodology for calculating qualifying payment amount.

(a) * * *

(18) *Downcode* means the alteration by a plan or issuer of a service code to another service code, or the alteration, addition, or removal by a plan or issuer of a modifier, if the changed code or modifier is associated with a lower qualifying payment amount than the service code or modifier billed by the provider, facility, or provider of air ambulance services.

* * * * *

(d) * * *

(1) * * *

(ii) If the qualifying payment amount is based on a downcoded service code or modifier—

(A) A statement that the service code or modifier billed by the provider, facility, or provider of air ambulance services was downcoded;

(B) An explanation of why the claim was downcoded, which must include a description of which service codes were altered, if any, and a description of which modifiers were altered, added, or removed, if any; and

(C) The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded;

* * * * *

(g) *Applicability date.* The provisions of this section are applicable for plan years or in the individual market, policy years beginning on or after January 1, 2022, except that paragraph (a)(18) of this section regarding the definition of the term ''downcode'' and paragraph (d)(1)(ii) of this section regarding additional information that must be provided if the qualifying payment amount is based on a downcoded service code or modifier are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market, policy years beginning on or after January 1, 2022.

■ 14. Section 149.510 is amended by:
■ a. Removing paragraph (a)(2)(viii);
■ b. Redesignating paragraphs (a)(2)(ix) through (xiii) as paragraphs (a)(2)(viii) through (xii), respectively; and
■ c. Revising paragraphs (c)(4)(ii)(A), (c)(4)(iii) and (iv), (c)(4)(vi)(B), (f)(1)(v)(F), and (h).

The revisions read as follows:

§ 149.510 Independent dispute resolution process.

* * * * *

(c) * * *

(4) * * *

(ii) * * *

(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, weighing only 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 that the certified IDR entity determines best represents the value of the qualified IDR item or service as the out-of-network rate.

* * * * *

(iii) *Considerations in determination.* In determining which offer to select:

(A) The certified IDR entity must consider the qualifying payment amount(s) for the applicable year for the same or similar item or service.

(B) The certified IDR entity must then consider information submitted by a party that relates to the following circumstances:

(*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.

(C) The certified IDR entity must also consider information provided by a party in response to a request by the certified IDR entity under paragraph (c)(4)(i)(A)(*2*) of this section that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(D) The certified IDR entity must also consider additional information submitted by a party that relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination and that does not include information on factors described in paragraph (c)(4)(v) of this section.

(E) In weighing the considerations described in paragraphs (c)(4)(iii)(B) through (D) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR item or service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR item or service, or it is already accounted for by the qualifying payment amount under paragraph (c)(4)(iii)(A) of this section or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section.

(iv) *Examples.* The rules of paragraph (c)(4)(iii) of this section are illustrated in the following paragraphs. Each example assumes that the Federal IDR process applies for purposes of determining the out-of-network rate, that both parties have submitted the information parties are required to submit as part of the Federal IDR process, and that the submitted information does not include information on factors described in paragraph (c)(4)(v) of this section:

(A) *Example 1*—(*1*) *Facts.* A level 1 trauma center that is a nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. The facility submits an offer that is higher than the qualifying payment amount. The facility also submits additional written information showing that the scope of services available at the facility was critical to the delivery of care for the qualified IDR item or service provided, given the particular patient's acuity. This information is determined to be credible by the certified IDR entity. Further, the facility submits additional information showing the contracted rates used to calculate the qualifying payment amount for the qualified IDR item or service were based on a level of service that is typical in cases in which the services are delivered by a facility that is not a level 1 trauma center and that does not have the capability to provide the scope of services provided by a level 1 trauma center. This information is also determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount. No additional information is submitted by either party. The certified IDR entity determines that all the information submitted by the nonparticipating emergency facility relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(A) (*Example 1*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the nonparticipating emergency facility, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. If the certified IDR entity determines that it is appropriate to give weight to the additional credible information submitted by the nonparticipating emergency facility and that the additional credible information submitted by the facility demonstrates that the facility's offer best represents the value of the qualified IDR item or service, the certified IDR entity should select the facility's offer.

(B) *Example 2*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information regarding the level of training and experience the provider possesses. This information is determined to be credible by the certified IDR entity, but the certified IDR entity finds that the information does not demonstrate that the provider's level of training and experience relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination (for example, the information does not show that the provider's level of training and experience was necessary for providing the qualified IDR service that is the subject of the payment determination to the particular patient, or that the training or experience made an impact on the care that was provided). The nonparticipating provider does not submit any additional information. The issuer submits an offer equal to the qualifying payment amount, with no additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(B) (*Example 2*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity must then consider the additional information submitted by the nonparticipating provider, provided the information relates to circumstances described in paragraphs (c)(4)(iii)(B) through (D) of this section and relates to the offer for the payment amount for the qualified IDR item or service that is the subject of the payment determination. In addition, the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the additional information submitted by the provider is credible but does not relate to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination, and determines that the issuer's offer best represents the value of the qualified IDR service, in the absence of any other credible information that relates to either party's offer, the certified IDR entity should select the issuer's offer.

(C) *Example 3*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process involving an emergency department visit for the evaluation and management of a patient. The provider submits an offer that is higher than the qualifying payment amount. The provider also submits additional written information showing that the acuity of the patient's condition and complexity of the qualified IDR service furnished required the taking of a comprehensive history, a comprehensive examination, and medical decision making of high complexity. This information is determined to be credible by the certified IDR entity. The issuer submits an offer equal to the qualifying payment amount for CPT code 99285, which is the CPT code for an emergency department visit for the evaluation and management of a patient requiring a comprehensive history, a comprehensive examination, and medical decision making of high complexity. The issuer also submits additional written information showing that this CPT code accounts for the acuity of the patient's condition. This information is determined to be credible by the certified IDR entity. The certified IDR entity determines that the information provided by the provider and issuer relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(C) (*Example 3*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but the certified IDR entity should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines the additional information on the acuity of the patient and complexity of the service is already accounted for in the calculation of the qualifying payment amount, the certified IDR entity should not give weight to the additional information provided by the provider. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(D) *Example 4*—(*1*) *Facts.* A nonparticipating emergency facility and an issuer are parties to a payment determination in the Federal IDR process. Although the facility is not participating in the issuer's network during the relevant plan year, it was a participating facility in the issuer's network in the previous 4 plan years. The issuer submits an offer that is higher than the qualifying payment amount and that is equal to the facility's contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The issuer also submits additional written

information showing that the contracted rates between the facility and the issuer during the previous 4 plan years were higher than the qualifying payment amount submitted by the issuer, and that these prior contracted rates account for the case mix and scope of services typically furnished at the nonparticipating facility. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the issuer for the payment amount for the qualified IDR service that is the subject of the payment determination. The facility submits an offer that is higher than both the qualifying payment amount and the contracted rate (adjusted for inflation) for the previous year with the issuer for the qualified IDR service. The facility also submits additional written information, with the intent to show that the case mix and scope of services available at the facility were integral to the service provided. The certified IDR entity determines this information is credible and that it relates to the offer submitted by the facility for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(D) (*Example 4*), the certified IDR entity must consider the qualifying payment amount. The certified IDR entity then must consider the additional information submitted by the parties, but should not give weight to information to the extent it is already accounted for by the qualifying payment amount or other credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity determines that the information submitted by the facility regarding the case mix and scope of services available at the facility includes information that is also accounted for in the information the issuer submitted regarding prior contracted rates, then the certified IDR entity should give weight to that information only once. The certified IDR entity also should not give weight to the same information provided by the nonparticipating emergency facility in relation to any other factor. If the certified IDR entity determines that the issuer's offer best represents the value of the qualified IDR service, the certified IDR entity should select the issuer's offer.

(E) *Example 5*—(*1*) *Facts.* A nonparticipating provider and an issuer are parties to a payment determination in the Federal IDR process regarding a qualified IDR service for which the issuer downcoded the service code that the provider billed. The issuer submits an offer equal to the qualifying payment amount (which was calculated using the downcoded service code). The issuer also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment (which describes why the service code was downcoded). The certified IDR entity determines this information is credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. The provider submits an offer equal to the amount that would have been the qualifying payment amount had the service code not been downcoded. The provider also submits additional written information that includes the documentation disclosed to the nonparticipating provider under § 149.140(d)(1)(ii) at the time of the initial payment. Further, the provider submits additional written information that explains why the billed service code was more appropriate than the downcoded service code, as evidence that the provider's offer, which is equal to the amount the qualifying payment amount would have been for the service code that the provider billed, best represents the value of the service furnished, given its complexity. The certified IDR entity determines this information to be credible and that it relates to the offer for the payment amount for the qualified IDR service that is the subject of the payment determination. Neither party submits any additional information.

(*2*) *Conclusion.* In this paragraph (c)(4)(iv)(E) (*Example 5*), the certified IDR entity must consider the qualifying payment amount, which is based on the downcoded service code. The certified IDR entity then must consider whether to give weight to additional information submitted by the parties. If the certified IDR entity determines that the additional credible information submitted by the provider demonstrates that the nonparticipating provider's offer, which is equal to the qualifying payment amount for the service code that the provider billed, best represents the value of the qualified IDR service, the certified IDR entity should select the nonparticipating provider's offer.

* * * * *

(vi) * * *

(B) The certified IDR entity's written decision must include an explanation of their determination, including what information the certified IDR entity determined demonstrated that the offer selected as the out-of-network rate is the offer that best represents the value of the qualified IDR item or service, including the weight given to the qualifying payment amount and any additional credible information under paragraphs (c)(4)(iii)(B) through (D) of this section. If the certified IDR entity relies on information described under paragraphs (c)(4)(iii)(B) through (D) of this section in selecting an offer, the written decision must include an explanation of why the certified IDR entity concluded that this information was not already reflected in the qualifying payment amount.

* * * * *

(f) * * *

(1) * * *

(v) * * *

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraphs (c)(4)(iii)(B) through (D) of this section;

* * * * *

(h) *Applicability date.* The provisions of this section are applicable with respect to plan years or in the individual market policy years beginning on or after January 1, 2022, except that the provisions regarding IDR entity certification at paragraphs (a) and (e) of this section are applicable beginning on October 7, 2021; and paragraphs (c)(4)(ii) through (iv) of this section regarding payment determinations, paragraph (c)(4)(vi)(B) of this section regarding written decisions, and paragraph (f)(1)(v)(F) of this section regarding reporting of information relating to the Federal IDR process are applicable with respect to items or services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

■ 15. Section 149.520 is amended by:
■ a. Revising paragraphs (b)(1) and (b)(2) introductory text;
■ b. Redesignating paragraph (b)(3) as paragraph (b)(4);
■ c. Adding a new paragraph (b)(3); and
■ d. Revising newly redesignated paragraph (b)(4)(iv)(F) and paragraph (c).

The addition and revisions read as follows:

§ 149.520 Independent dispute resolution process for air ambulance services.

* * * * *

(b) * * *

(1) *In general.* Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group

or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(2) *Considerations for air ambulance services.* In determining which offer to select, in addition to considering the applicable qualifying payment amount(s), the certified IDR entity must consider information submitted by a party that relates to the following circumstances:

* * * * *

(3) *Weighing considerations.* In weighing the considerations described in paragraph (b)(2) of this section, the certified IDR entity should evaluate whether the information is credible and relates to the offer submitted by either party for the payment amount for the qualified IDR service that is the subject of the payment determination. The certified IDR entity should not give weight to information to the extent it is not credible, it does not relate to either party's offer for the payment amount for the qualified IDR service, or it is already accounted for by the qualifying payment amount under § 149.510(c)(4)(iii)(A) or other credible information under § 149.510(c)(4)(iii)(B) through (D), except that the additional circumstances in § 149.510(c)(4)(iii)(B) shall be understood to refer to paragraph (b)(2) of this section.

(4) * * *

(iv) * * *

(F) The rationale for the certified IDR entity's decision, including the extent to which the decision relied on the criteria in paragraph (b)(2) of this section and § 149.510(c)(4)(iii)(C) and (D);

* * * * *

(c) *Applicability date.* The provisions of this section are applicable with respect to plan years, or in the individual market, policy years, beginning on or after January 1, 2022, except that paragraphs (b)(1), (2), and (3) and (b)(4)(iv)(F) of this section regarding payment determinations are applicable with respect to services provided or furnished on or after October 25, 2022, for plan years or in the individual market policy years beginning on or after January 1, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2023, I electronically filed the foregoing record excerpts with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

s/ Kevin B. Soter
Kevin B. Soter