In the

Supreme Court of the United States

SALOOJAS, INC.,

Petitioner,

v.

AETNA HEALTH OF CALIFORNIA, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

Michael L. Gabriel, Esq. Counsel of Record 1903 A Cooley Avenue East Palo Altos, CA 94303 (650) 888-9189 aetal@earthlink.net

 $Counsel \ for \ Petitioner$



I. QUESTION PRESENTED

Did Congress have an implicit intent to create a private remedy in favor of diagnostic testing providers for full reimbursement under the CARES Act?

II. CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the undersigned counsel of record for Petitioner SALOOJAS, INC., hereby certifies that SALOOJAS, INC., is incorporated and does not have any parent companies, subsidiaries, or affiliates that have issued shares to the public.

III. PARTIES TO THE PROCEEDINGS AND RELATED CASES

SALOOJAS, INC., Petitioner, v. AETNA HEALTH OF CALIFORNIA, INC., Respondents. Below are cases directly related to the case in this Court:

- * Saloojas, Inc vs. Aetna Health of California, Inc, No: 22-16034, No: 22-16035, No: 22-16036, No: 22-16037, No: 22-16038, United States Court Appeals for the Ninth Circuit.
- * Saloojas, Inc vs. Aetna Health of California, Inc, No. 22-cv-01696 JSC. U.S. District Court for Northern District of California Judgment entered August 17, 2022.
- * Saloojas, Inc vs. Aetna Health of California, Inc, No. 22-cv-01702-JSC.U.S. District Court for Northern District of California Judgment entered August 17, 2022. Notice of Appeal July 15, 2022,
- * Saloojas, Inc vs. Aetna Health of California, Inc, No. 22-cv-01703-JSC. U.S. District Court for Northern District of California Judgment entered August 17, 2022.
- * Saloojas, Inc vs. Aetna Health of California, Inc, No. 22-cv-01704-JSC. U.S. District Court for Northern District of California Judgment entered August 17, 2022.

- * Saloojas, Inc vs. Aetna Health of California, Inc, No. 22-cv-01706-JSC. U.S. District Court for Northern District of California Judgment entered August 17, 2022.
- * Saloojas, Inc vs. Aetna Health of California, Inc No: 21SC004114. The State of California, Alameda County Superior Court Small Claims Division
- * Saloojas, Inc vs. Aetna Health of California, Inc No: 21SC004108 The State of California, Alameda County Superior Court Small Claims Division
- * Saloojas, Inc vs. Aetna Health of California, Inc No: 21SC004106. The State of California, Alameda County Superior Court Small Claims Division
- * Saloojas, Inc vs. Aetna Health of California, Inc No: 21SC004104. The State of California, Alameda County Superior Court Small Claims Division
- * Saloojas, Inc vs. Aetna Health of California, Inc No: 21SC004091. The State of California, Alameda County Superior Court Small Claims Division

IV. TABLE OF CONTENTS

Page
I. QUESTION PRESENTEDi
II. CORPORATE DISCLOSURE STATEMENT ii
III. PARTIES TO THE PROCEEDINGS AND RELATED CASESiii
IV. TABLE OF CONTENTSv
V. TABLE OF APPENDICES viii
VI. TABLE OF CITED AUTHORITIESix
VII. PETITION FOR WRIT OF CERTIORARI 1
VIII. OPINIONS BELOW
IX. JURISDICTION1
X. CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED
XI. STATEMENT OF THE CASE2
A. The Court Should Grant Expedited Review
B. Health Care Providers Have An Implied Private Right Of Action for Private Remedy Under The CARES Act.

$Table\ of\ Contents$

	I	Page
С.	Statement of Facts	5
	1. Due To The Need For Immediate And Efficient Testing, Congress Enacted The FFCRA And CARES Act So Patients Could Easily Get Tested And Providers Would Be Fully Compensated During The Pandemic	6
	2. To Combat The National Pandemic, The Petitioner Invested in Creating Testing Sites At The Very Start Of The Pandemic	8
	3. Aetna Circumvented and Undermined Federal Law Reflected in the CARES Act	9
D.	Procedural History	. 10
XII. F	REASON FOR GRANTING THE PETITION.	. 12
A.	This Case Warrants This Court's Review	. 12
	Factor 1. Is Plaintiff in a Class the Statutes Intended to Benefit?	. 14
	Factor 2. Is There Evidence of Legislative Intent to Create or Deny a Private Right of Action?	16

vii

$Table\ of\ Contents$

Page
Factor 3. Is a Private Right of Action in Favor of Plaintiff Consistent with the Legislative Scheme?
Factor 4. Would It Be Inappropriate to Create a Federal Right, Given the Context of State Concerns?
1. The Lower Courts Have Erred in the Opinions Below, and Such Errors Must Be Corrected To Ensure Public Safety and Save Lives
2. Health Care Providers Have An Implied Private Right Of Action for Private Remedy Under The CARES Act
a. The CARES Act26
b. Congress Sought to Rapidly Increase Access to COVID-19 Testing Creating a Reimbursement Right Without Written Remedy Favoring An Implied Right Consistent with the Purpose of the CARES Act
XIII. CONCLUSION

viii

V. TABLE OF APPENDICES

Po	age
APPENDIX A — ORDER OF THE UNITED	
STATES DISTRICT COURT FOR THE	
NORTHERN DISTRICT OF CALIFORNIA,	
FILED JUNE 23, 2022	.1a
APPENDIX B — RELEVANT STATUTORY	
PROVISIONS	16a

VI. TABLE OF CITED AUTHORITIES

Page
CASES
Alexander v. Sandoval, 532 U.S. 275 (2001)
Am. Video Duplicating, Inc. v. City Nat'l Bank, 2020 WL 6882735 (C.D. Cal. Nov. 20, 2020)
Ashcroft v. Iqbal, 556 U.S. 662 (2009)20
Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)
Cannon v. University of Chicago, 441 U.S. 677 (1979)
Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, 467 U.S. 837 (1984)
Cort v. Ash, 422 U.S. 66 (1975)passim
Diagnostic Affiliates of Ne. Hou, LLC v. United Healthcare Servs., 2022 WL 214101 (S.D. Tex. Jan. 18, 2022) \dots 12, 13, 23
Franklin v. Gwinnett County Pub. Schs., 503 U.S. 60 (1992)

$Cited\ Authorities$

Page
Graham v. Bhd. of Locomotive Firemen & Enginemen, 338 U.S. 232 (1949)
Hawaii Motor Sports Center v. Babbitt, 125 F. Supp. 2d 1041 (D. Haw. 2000)
Int'l Bhd. of Elec. Workers v. Foust, 442 U.S. 42 (1979)
Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31, 138 S. Ct. 2448 (2018)
Leonard F. v. Israel Disc. Bank of N.Y., 199 F.3d 99 (2d Cir. 1999)
Lindsay v. Ass'n of Prof'l Flight Attendants, 581 F.3d 47 (2d Cir. 2009)
M.F. v. State of New York Exec. Dep't Div. of Parole, 640 F.3d 491 (2d Cir. 2011)24
Maine Comm. Health v. US Mod. Health Plan, 140 S. Ct. 1308 (2020)13, 14, 16
Merrill Lynch, Pierce, Fenner & Smith, v. Curran, 456 U.S. 353 (1982)24

$Cited\ Authorities$

Page
$\begin{array}{c} \textit{Murphy Med. Assocs., LLC v.} \\ \textit{Cigna Health \& Life Ins.,} \\ \textit{No. 3:20cv1675(JBA), 2022 WL 743088} \\ \textit{(D. Conn. Mar. 11, 2022)} & \dots & \dots & 13, 19, 21 \end{array}$
Oxford Univ. Bank v. Lansuppe Feeder, 933 F.3d 99 (2d Cir. 2019)
Patane v. Clark, 508 F.3d 106 (2d Cir. 2007)
Republic of Iraq v. ABB AG, 768 F.3d 145 (2d Cir. 2014)24
San Juan Cable LLC v. P. R. Tel. Co., 612 F.3d 25 (1st Cir. 2010)
Steele v. Louisville & N.R. Co., 323 U.S. 192 (1944)
Transamerica Mortg. Advisors, (TAMA) v. Lewis, 444 U.S. 11 (1979)
United States v. Langston, 118 U.S. 389 (1886)
Villager Pond, Inc. v. Town of Darien, 56 F.3d. 375 (1995)

xii

Cited Authorities

Page
STATUTES AND CONSTITUTIONAL PROVISIONS
28 U.S.C. § 1254(1)
28 U.S.C. § 1331
28 U.S.C. § 1441(a)
28 U.S.C. § 2101(e)
The Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub. L. 116-136 (2020) the "CARES Act" passim
Families First Coronavirus Response Act ("FFCRA"), Pub. L. No. 116-127, 134 Stat. 178 (March 18, 2020)
RULES
Fed. R. Civ. P. 8(a)(2)
Fed. R. Civ. P. 12(b)(6)10

VII. PETITION FOR WRIT OF CERTIORARI

PETITIONER SALOOJAS, INC., by and through Michael L. Gabriel, Attorney for Petitioner, respectfully requests that this court issue a writ of certiorari to reverse and remand the decision from The Northern District of California issued an order in Saloojas, Inc. v. Aetna Health of California, Inc., No. 22-CV-01696-JSC, 2022 WL 2267786 (N.D. Cal. June 23, 2022), which held there is no private cause of action under The CARES Act.

VIII. OPINIONS BELOW

The Northern District of California issued the order in this instant case, *Saloojas*, *Inc. v. Aetna Health of California*, *Inc.*, No. 21-cv-01696-JSC [lead case number], 2022 WL 2267786 (N.D. Cal. June 23, 2022), holding that there is no private cause of action and remedy under the CARES Act. In doing so, the court granted Aetna Health of California, Inc.,'s Motion to Dismiss, which disposed of the matter in its entirety. [Order Granting Motion to Dismiss, June 23, 2022, Appendix 1a].

IX. JURISDICTION

Most recent opinion was issued on June 23, 2022. Notice of Appeal was filed in the Ninth Circuit Court of Appeals on July 15, 2022, which is matter is pending. Therefore, this federal case is invoked under 28 U.S.C. § 1254(1). Pursuant to 28 U.S.C. § 2101(e), Petitioner seeks this application to the Supreme Court for a writ of certiorari to review the case before judgment has been rendered in the court of appeals, which is timely and made prior to judgment being issued.

X. CONSTITUTIONAL, STATUTORY, AND REGULATORY PROVISIONS INVOLVED

The Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub. L. 116-136 (2020) the "CARES Act", which was passed by Congress. Appendix 16a

Section 6001 of the Families First Coronavirus Response Act ("FFCRA"), as amended by Section 3201 of the CARES Act. Appendix 21a.

XI. STATEMENT OF THE CASE

A. The Court Should Grant Expedited Review.

The court should grant expedited review of this writ to settle the conflict of jurisdictions. Three other states have motions to dismiss pending which need Supreme Court resolution to settle the issue of who can enforce the Cares Act. The three states are as follows: New Jersey: OPEN MRI AND IMAGING OF RP VESTIBULAR DIAGNOSTICS, P.A., vs. CIGNA HEALTH AND LIFE INSURANCE COMPANY, Case No: 2:20-CV-10345-KMSK: Minnesota: GS LABS, LLC, v. MEDICA INSURANCE COMPANY, Case Number: No.: 21-cv-2400; Washington PREMERA BLUE CROSS v. GS LABS, LLC, Case No. 2:21-cv-01399-LK.

There is a growing emergency with the resurgence of the pandemic for which the CARES ACT is front and center in the COVID treatment. By granting this writ, the court can save more lives than most physicians will save in their entire career.

In 2020 during the prior Trump Administration, the insurance companies adhered to the Cares Act thereby keeping the rate of people who died of COVID to approximately 350,381 people according to the CDC figures. Thereafter, January 2021 at the onset of the Biden Administration wherein the Cares Act was no longer enforced, insurance companies stopped reimbursing health care providers in full as required by the Cares Act. Petitioner in this matter could not get his services reimbursed in April 2021. Instead, Aetna forced Petitioner to navigate mountains of paper and bureaucracy to delay and obstruct reimbursement. The Cares Act was specifically enacted to avoid this conduct by insurers. Now that the Cares Act is no longer enforced, the number of COVID Deaths have nearly tripled to well over one million. The difference can be attributed to insurance companies not paying for medical testing services in violation of the Cares Act. This is a real emergency situation for which the Supreme Court is needed immediately to settle the law on a national COVID medical policy so that people do not die unnecessarily.

B. Health Care Providers Have An Implied Private Right Of Action for Private Remedy Under The CARES Act.

This is an action seeking congressionally-mandated reimbursement for the full price of lifesaving COVID-19 diagnostic testing services that Petitioner Saloojas, Inc., provided to insureds of Respondent Aetna Health of California, Inc.

Congress took the extra ordinary step of enacting Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), and Section 6001 of the Families First Coronavirus Response Act ("FFCRA"), as amended by Section 3201 of the CARES Act to reduce the pandemic's harm by ensuring that any person who needed a test could get one. Appendix 16a, 21a. Congress addressed such concern by requiring all health insurance plans to cover COVID-19 testing with no out of pocket expenses to patients. The acts sought to make certain that no person would have to consider the economic cost of getting tested, and so co-payments, deductibles, and co-insurance were prohibited. In doing so, Congress mandated that insurers like Aetna "shall reimburse the provider of the diagnostic testing." Despite such mandate, Aetna has refused to do so, and such refusal jeopardizes public safety and violates the intent of Congress.

It was the need to get tested for COVID which gave cause for Congress to enact the CARES Act and such reason still exists today. The need is exemplified in a message issued by the White House, which states: "The American people deserve an urgent, robust, and professional response to the growing public health and economic crisis caused by the coronavirus (COVID-19) outbreak. President Biden believes that the federal government must act swiftly and aggressively to help protect and support our families, small businesses, first responders, and caregivers essential to help us face this challenge, those who are most vulnerable to health and economic impacts, and our broader communities – not to blame others or bail out corporations. President Biden and Vice President Harris have a seven-point plan to beat COVID-19. Ensure all Americans have access to regular, reliable, and free testing."

There is now a split in the jurisdictions between two United States District Courts as whether there is a private of right of action to enforce the will of Congress for free COVID testing necessary to save lives. This division reveals a conflict in jurisdictions wherein the Texas District Court and the Connecticut and California District Courts have conflicting orders. The Texas District Court ruled a private right of action does exist, and the Connecticut and California District Courts rules there is not a private remedy available. There are three other states wherein motions to dismiss on this very question of law is pending. Thus, showing a need for Supreme Court resolution. Furthermore, there is a growing emergency stemming from the resurgence of the pandemic for which the enforcement of The CARES Act is necessary to save lives. Therefore, United States Supreme Court should review this case to enforce The CARES Act to ensure "free testing", which is needed to prevent more deaths from COVID and save lives.

C. Statement of Facts

In early 2020 the COVID-19 pandemic quickly set upon the United States. Due to the hyperbolic onset of COVID-19, California, and the rest of the country, were unprepared in many critical aspects. By late March of 2020, the COVID-19 outbreak, was ravaging the country as America's worst pandemic in over 100 years. The COVID-19 illness was easily spread by an infected person, even before symptoms developed. Any effort to contain the disease required testing as many Americans as possible. Rapid testing was needed to identify those infected to provide prompt treatment. Such rapid testing was required so that infected people would quarantine themselves to

prevent infection of this highly communicable disease. In response, the United States Congress and the President of the United States agreed that immediate and drastic action was necessary. The Government took the extra ordinary step of enacting a pair of statutes to reduce the pandemic's harm by ensuring that any person who needed a test could get one.

1. Due To The Need For Immediate And Efficient Testing, Congress Enacted The FFCRA And CARES Act So Patients Could Easily Get Tested And Providers Would Be Fully Compensated During The Pandemic.

On March 27, 2020, the President signed into law the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Pub. L. 116-136 (2020) (the "CARES Act", which was passed by Congress. Congress enacted legislation to help the country fight the virus. Congress enacted the CARES Act. Taken together, these statutes required all health insurance plans to cover COVID-19 testing with no out-of-pocket expenses to patients. These statutes allowed patients to have access to a COVID-19 test that was provided by a practice that was not in the patient's insurance. Both the FFCRA and the CARES Act addressed how insurers were required to reimburse both "in- network" and "out-of-network providers." In a section titled "ACCESS TO HEALTH CARE FOR COVID-19 PATIENTS," the CARES Act added a requirement that health plans covered by the FFCRA "shall reimburse the provider of the diagnostic testing as follows . . ." for covered tests and services. The Act then set forth alternative methods to calculate the actual payment amounts health plans were required to pay

providers for testing and other services. Importantly, the Act addressed payment for services provided by "out-of-network" providers and "in-network" providers. To be more precise, under the legislation, if the patient's plan already had a negotiated rate with the provider, i.e., the provider was "in-network," the plan had to pay that negotiated rate. Furthermore, the Act also addressed the payment requirements for providers who did not have a negotiated rate, i.e., "out-of-network providers." Insurers were required to pay "out of network" providers their full cash price for the test unless the insurer could negotiate a lower rate with the provider. In addition to reimbursing providers for the COVID tests, insurers were to reimburse providers for other related tests, items, and services furnished during a visit that resulted in an order for a COVID-19 or COVID-19 anti body test.

The acts sought to make certain that no person would have to consider the economic cost of getting tested, and so co-payments, deductibles, and co-insurance were prohibited. Removing barriers that might discourage patients from getting tested was only part of the goal - Congress also needed to persuade practitioners to participate and invest in establishing testing centers that would test anyone. This included making sure that providers would not turn away patients who had insurance coverage, but the coverage was through a plan in which the provider was not a contracted participant, i.e., was "out-of-network." Congress addressed both in- network and out-of-network providers directly, by requiring plans to cover testing from out-of-network providers on the same terms as from in-network providers. These express terms were that there would be no out of pocket expenses, no co-payments, and no deductibles. Congress recognized, however, that plans often pay very little to out-of-network providers, something they do to incentivize their members to use in-network providers who have agreed by contract to accept discounted rates. In order to prevent providers from declining to provide testing services to patients who were out-of-network with respect to the providers, Congress set out a specific reimbursement protocol for out-of-network providers, which required plans pay such providers their cash price, unless a lower price had been negotiated.

2. To Combat The National Pandemic, The Petitioner Invested in Creating Testing Sites At The Very Start Of The Pandemic.

Petitioner were among the earliest pioneers in the effort, establishing testing centers to provide around the clock opportunities for residents of Northern California to get tested. Their efforts included testing over 35,000 patients and provided no-cost testing to over 3,000 uninsured patients. Petitioner were hailed by local leaders such as the Mayor of Newark, California.

In doing so, Petitioner invested hundreds of thousands of dollars to transform its traditional medical practice to setup COVID-19 testing sites for walk in patients. These sites – which were erected virtually overnight – were designed to provide efficient drive and/or walk-through COVID-19 testing to patients with symptoms or suspected exposure. This was the first line of defense against the pandemic. Petitioner operated drive and/or walk-through COVID-19 testing site in Newark, California. In addition to creating the physical infrastructure for the testing sites, Petitioner had to assemble the clinical and

administrative staff needed to operate the sites. Similarly, it had to develop extensive protocols and procedures to ensure the sites were effectively and efficiently operating, and that all safety, infection control, OSHA, and CDC guidance were observed. Petitioner's efforts to drastically increase testing in the area were a key and valuable part of the population's defenses against COVID-19.

3. Aetna Circumvented and Undermined Federal Law Reflected in the CARES Act.

In its response to the national emergency, Aetna did not embrace the coordinated approach to testing developed by Congress. Instead, Aetna looked to protect their bottom-line by engaging in a campaign to undermine and circumvent federal policy and federal law as reflected in the FFCRA and the CARES act, as well as the guidance issued by federal agencies. Aetna refused to honor its coverage requirements under federal legislation by routinely refusing to pay providers. Consequently, providers were not fully paid for their services though federal law required Aetna to provide full reimbursement. Providers challenged Aetna's refusals and their response was essentially, "tough luck – there is nothing you can do about it."

Aetna's refusal to pay for rendered COVID testing services were expressly prohibited. Aetna has denied reimbursement for COVID-19 testing and testing-related services for thousands of Aetna's members or beneficiaries.

Aetna still owes more than \$1 million dollars to Petitioner for its rendered COVID testing services.

D. Procedural History

On December 14, 2021, Petitioner filed a complaint in the Small Claims Division of the Superior Court of California, County of Alameda. The Complaint sought money that was owed by Aetna Health of California and punitive damages.

In the Complaint, Petitioner set forth that they provided COVID-19 testing, which was not paid by Aetna, and such lack of payment was "an intentional violation of the CARES ACT." Further, that Petitioner underwent Aetna's appeal process, resulting in a denial of full payment mandated under the CARES ACT.

Aetna was served with the Complaint on February 15, 2022, and on March 16, 2022, it removed the case pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1441(a) on grounds that the alleged money owed to Petitioner was pursuant to the provision of a federal statute.

Once removed to the Northern District, Aetna moved to have the Complaint dismissed arguing that no private cause of action or relief exists under the CARES Act. In doing so, Aetna successfully had the Complaint be dismissed with prejudice pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. In their Motion, Aetna attempted to circumvent federal law by arguing that there is no private right of action under the FFCRA or the CARES Act, seeking dismissal of Plaintiff's Complaint.

Aetna cited cases rejecting attempts to privately enforce "various provisions" of the over 300 pages CARES Act. However, not one of the cases cited addressed the

specific provision of the CARES Act that the Petitioner sought to enforce. As noted, the CARES Act is over 300 pages of legislation of which only two pages are devoted to COVID-19 testing. The bulk of the Act addresses economic relief and stimulus programs. Aetna's cases failed to address the issue before the Court – whether Part II, Subpart A, Section 3201of the CARES Act permits out-of- network providers to sue insurers to collect reimbursement payments. Instead, the cases cited by Aetna only concerned payroll protection loans and other legislation to assist small businesses. Am. *Video Duplicating, Inc. v. City Nat'l Bank*, No. 20-cv-04036, 2020 WL 6882735, at *1 (C.D. Cal. Nov. 20, 2020) (concerns Paycheck Protection Program and the right of an agent to collect fees).

Petitioner's opposition argued that a private right of action can readily be inferred from the language and context of the CARES Act establishing the provider's right to reimbursement for the COVID testing services it provided in both its Memorandum of Law In Opposition to Defendant's Motion to Dismissal and its Supplemental Brief in Support of Opposition to Motion to Dismiss Plaintiff's Complaint for Failure to State a Claim.

On June 23, 2022, the Northern District of California issued the order in this instant case, *Saloojas, Inc. v. Aetna Health of California, Inc.*, No. 22-CV-01696-JSC, 2022 WL 2267786 (N.D. Cal. June 23, 2022), holding that there is no private cause of action under the CARES Act. In doing so, the Court granted Aetna's Motion to Dismiss, which dismissed the matter in its entirety.

The Saloojas Decision states without explanation that there is no indication of intent. Thus, failing to recognize evidence of Congress's explicit or implicit intent to create a remedy. The Decision further fails to provide full analysis of the law.

Consequently, Petitioner herein seeks urgent relief. Petitioner believes this decision fails to fully consider the text, structure, and legislative history of the CARES Act, all of which demonstrate that Congress intended to create a private remedy in favor of diagnostic testing providers.

XII. REASON FOR GRANTING THE PETITION

A. This Case Warrants This Court's Review

There is a conflict of law in the District Courts, and this case is an ideal vehicle to resolve such conflict. The legal issues are of importance even beyond the scope of the present case and is of great national significance as it relates to a private right of action under the Cares Act to enforce public safety to save lives. By granting this writ, the court can save more lives than most physicians will save in their entire career

Until this instant case, there have been only two cases addressing whether an out of network provider can bring a private suit for nonpayment under the CARES Act. There is now a split in the jurisdictions. The two cases that have addressed whether an implied right of action exists for a testing reimbursement claim under the CARES Act were in the Texas District Court in *Diagnostic Affiliates of Ne. Hou, LLC v. United Healthcare Servs., Inc.*, No. 2:21-CV-00131, 2022 WL 214101, at *4–9 (S.D. Tex. Jan. 18, 2022),

Civ Act found that a private right of action exists, while in *Murphy Med. Assocs.*, *LLC v. Cigna Health & Life Ins. Co.*, No. 3:20cv1675(JBA), 2022 WL 743088, at *2–6 (D. Conn. Mar. 11, 2022), the Connecticut Court held that a private right of action did not exist because essentially it was not expressly stated by Congress. Though the Connecticut Court referenced the Texas District Court's ruling in *Diagnostic Affiliates of Northeast Houston, LLC vs. United Health Care Service*, it was not fully addressed.

This Court in a case of a nearly identical issue of whether Congress imposed a liability and obligation to pay under the Patient Protection and Affordable Care Act was relied upon by the Texas court *Maine Comm. Health v. US Mod. Health Plan, Inc.*, 140.S.Ct. 1320, 1320 (2020), which stated:

"Congress can also create an obligation directly by statute, without also providing details about how it must be satisfied. Consider, for example, *United States v. Langston*, 118 U.S. 389, 6 S.Ct. 1185, 30 S.Ct. 164 (1886). In that case, Congress had enacted a statute fixing an official's annual salary at "\$7,500 from the date of the creation of his office." Id., at 394, 6 S.Ct. 1185. Years later, however, Congress failed to appropriate enough funds to pay the full amount, prompting the officer to sue for the remainder. Id., at 393, 6 S. Ct. 1185. Understanding that Congress had created the obligation by statute, this Court held that a subsequent failure to appropriate enough funds neither "abrogated [n] or suspended" the Government's pre-existing commitment to pay. Id., at 394, 6 S.Ct. 1185. The Court thus affirmed judgment for the officer for the balance owed. Ibid.5"

The Texas Court looked at this US Supreme Court case and concluded that Congress intended to impose the liability on insurance companies for payment to out- ofnetwork providers such as Petitioner for their rendered Covid testing services. The issue was then to decide whether there was also an implied private right of action giving such out of network providers the ability to sue for nonpayment under the CARESAct. To then make the decision as to whether a private right of action existed, the Texas Court then went on to apply the Supreme Court test as set forth in *Cort v. Ash*, 422 U.S. 66, 78 (1975) (citations omitted) for determining whether a private right of action was implied. In doing so, the Texas Court identified four factors to consider in determining whether a private remedy is implicit in a statute not expressly providing one as set forth below:

Factor 1. Is Plaintiff in a Class the Statutes Intended to Benefit?

The court found it was clear that the legislative objective was to ensure that COVID-19 testing was widely available to the entire population. This required that providers be willing to supply and administer the tests, which in turn required a reliable method of payment for that service. Payment of providers was sufficiently essential for the legislature to create a mandatory scheme, using the term "shall," for determining the amount to be paid and protecting patients from any burden associated with the cost or other administrative requirements. The FFCRA and CARES Act directly apply to Covid testing services and the mandatory reimbursement language in favor of testing providers supports finding an implied private right of action for the claims. See Maine Cmty.

Health Options v. United States, 140 S. Ct. 1308, 1320 (2020). That the plain language of the statutes indicated that Diagnostic Affiliates was among the class of providers for whose benefit the payment provisions were included. The Court's view of the mandatory language of the statutes for purposes of creating a private right of action should not be read to foreclose any defense or counterclaim challenging the propriety of Diagnostic Affiliates' pricing as such issue was not before the Court.

In Diagnostic Affiliates, the Defendants asserted that the FFCRA and the CARES Act were intended to benefit patients only. And an out-of-network provider may routinely assert its claim through an insured patient's rights under the applicable group health plan. D.E. 121, p. 6. However, the Court found this construction of the rights and remedies in the statutes failed to account for the fact that patients were to be spared any cost or administrative burden in obtaining COVID-19 testing. No plan coverage decision is necessary because the FFCRA requires coverage. No rate decision is necessary because the CARES Act prescribes the method for determining the rate. Therefore, there is no reason to involve the patient in the enforcement of the claim.

The Texas Court concluded that the FFCRA and CARES Act do intend to benefit patients. But to effectuate that, it also intends to benefit testing providers. These are not mutually exclusive concepts.

Factor 2. Is There Evidence of Legislative Intent to Create or Deny a Private Right of Action?

The Court found that the terms of the statutes, themselves, evidence legislative intent as follows: The mandatory nature of the reimbursement right supports recognition of an implied private right of action. See Maine Cmty. Health Options, 140 S. Ct. at 1320. Envision argues against that proposition, citing Hawaii Motor Sports Centerv. Babbitt, 125 F. Supp. 2d 1041, 1047 (D. Haw. 2000) as stating that mandatory language does not automatically imply a private right of action. But the Court does not treat the mandatory language as dispositive. Consistent with the analysis in *Hawaii Motor Sports*, the mandatory language is one aspect to consider when doing the fourpart Cort review. Id. n.3. In Hawaii Motor Sports, the mandatory language was unavailing because the claimant was not the intended beneficiary of the statute at issue. Here, Diagnostic Affiliates is an intended beneficiary and the mandatory language works in its favor.

Finding also that the Secretaries of Health and Human Services, Labor, and Treasury are empowered to implement the relevant FFCRA provisions through sub-regulatory guidance, program instruction or otherwise. FFCRA § 6001(c). And the same Secretaries are directed to enforce them through ERISA and the regulation and taxation of group health plans. FFCRA § 6001(b). But FFCRA § 6001 is relevant here because it requires insurers to cover COVID-19 testing through their health insurance plans. This provision indicates who is responsible for payment, not how payment is to be made. Its enforcement scheme is appropriately designed for the purpose of ensuring coverage for insureds. Nothing in

the amended complaint indicates Defendants have denied or reduced claims because the service is not covered or that it was provided to a person who was not an insured.

Defendants in the Texas case relied on the concept that, "The express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Alexander v. Sandoval*, 532 U.S. 275, 290 (2001). But the court found that the administrative enforcement provisions address other provisions and do not address the manner in which a COVID-19 testing provider can obtain its reimbursements (which are no less mandatory). Therefore, the administrative enforcement scheme cannot be said to evidence an intent to deny a private right of action.

Defendants also contended that the express creation of private enforcement rights for other provisions of the statutes indicates that the legislature would have likewise created a private enforcement right for reimbursement, had one been intended. D.E. 67, p. 7 ("Sections 3102, 5102, and 5105 of the FFCRA expressly incorporate the private enforcement provisions of Fair Labor Standards Act and Family and Medical Leave Act to remedy improper denials of emergency paid employee leave."). Diagnostic Affiliates responded that the lack of specificity in creating a private right of action for reimbursement was likely the result of the speed with which Congress had to act in response to the pandemic emergency. These statutes broadly address multifaceted aspects of the pandemic. Under the circumstances, seeking consistency in the treatment of remedies elevates form over substance where clear rights to reimbursement were created and no other enforcement mechanism exists. An implied private right of action is a more appropriate construction of the statute than the creation of a right without any remedy. The terms of the FFCRA and CARES Act support finding an implied private right of action to enforce the right to reimbursement for COVID-19 testing against insurance plans and administrators.

Factor 3. Is a Private Right of Action in Favor of Plaintiff Consistent with the Legislative Scheme?

The Court found that Congress wanted widespread COVID-19 testing, which could only be accomplished by private entities quickly incurring the cost of establishing testing sites across the country and procuring the necessary supplies to administer tests. Legislative impatience with the finer points of the relationship between providers and insurance companies to properly allocate those costs or to determine appropriate pricing is evidenced by the inclusion of a mandatory methodology for determining the rate to be paid, if the parties did not have the time or cooperation to negotiate rates. A private right of action to recover the mandated reimbursement is fully consistent with the legislative scheme.

Factor 4. Would It Be Inappropriate to Create a Federal Right, Given the Context of State Concerns?

The court determined that no state concerns counsel against recognizing an implied private right of action as a remedy to redress a federally-created right.

In conclusion, the Texas court in its Diagnostic Affiliates decision applied this Supreme Court's test and concluded that a private right of action existed for an out of network provider so as to be able to sue to enforce the CARES Act.

In sharp contrast, the Connecticut Court barely discussed the Supreme Court test in its *Murphy Medical decision* and ruled only on the basic premise that unless the Congress expressly provides a private right of action it does not exist, and declined to find a private cause of action.

When everything is considered, and the *Cort* factors properly applied, the only reasonable conclusion is that there is an implied private right of action under the CARES Act independent from the right of action derived from ERISA and RICO.

Respectfully, this Court should rule that these emergency laws passed in the midst of public health emergency have special exception, and confer standing to Petitioner, and other similarly situated providers, to pursue this remedy under the CARES Act.

1. The Lower Courts Have Erred in the Opinions Below, and Such Errors Must Be Corrected To Ensure Public Safety and Save Lives.

The Order in Saloojas, Inc. v. Aetna Health of California, Inc., No. 22-CV-01696-JSC, 2022 WL 2267786 (N.D. Cal. June 23, 2022), which held there is no private cause of action under the CARES Act failed to fully consider the text, structure, and legislative history of the CARES Act. Although the Saloojas Decision agreed that three of the four Cort factors favor finding a private cause of action, the decision does not address any of the arguments on the most relevant factor.

Whether there is evidence of Congress's explicit or implicit intent to create a remedy. The Court granted Aetna's motion to dismiss, which disposed of the matter in its entirety.

In granting Aetna's motion to dismiss, the Court failed to adhere to the legal standard for a motion to dismiss. A motion to dismiss under Rule 12(b)(6) must be decided on "facts stated on the face of the complaint, in documents appended to the complaint or incorporated in the complaint by reference, and matters of which judicial notice may be taken." Leonard F. v. Israel Disc. Bank of N.Y., 199 F.3d 99, 107 (2d Cir. 1999). In deciding a motion to dismiss, well-pleaded facts must be accepted as true and considered in the light most favorable to the Plaintiff. Patane v. Clark, 508 F.3d 106, 111 (2d Cir. 2007). The issue in deciding a motion to dismiss is "not whether the plaintiff will ultimately prevail but whether the plaintiff is entitled to offer evidence to support the claims." Villager Pond, Inc. v. Town of Darien, 56 F.3d. 375 (1995). The Court's ruling to dismiss, disposed of the matter. Consequently, Petitioners were prevented from presenting any evidence or further argument that they are entitled to reimbursement for their services under the CARES Act.

A complaint is only required to contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint must include "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference

that the defendant is liable for the misconduct alleged." *Id.* A complaint states a claim if it "raise[s] a reasonable expectation that discovery will reveal evidence" in support of the claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007).

Aetna's motion to dismiss failed for lack of legal authority. Aetna attacks the federal claims of the CARES Act based upon a handful of district court cases that have analyzed entirely unrelated parts of the CARES Act, which legislation exceeds 335 pages. The cases they cite are inapposite to establish that the particular statutory provision at issue in this case arguing that the relevant sections of the CARES Act does not support an implied private cause of action. In fact, Aetna's motion to dismiss all of these claims actually serves to reinforce a finding that an implied cause of action exists under the CARES Act (per the second Cort factor, see infra Part I.B) because, if Aetna were correct, providers would be left wholly without any remedy whatsoever. Accordingly, the Court should have denied Aetna's motion to dismiss. However, the Court granted the motion relying on the decision of Murphy Medical.

Petitioner respectfully submits that Murphy Medical decision is not persuasive for the following reasons:

First, the Murphy Medical decision does not address and analyze each of the four Cort factors, whereas the opinion in Diagnostic Affiliates, and GS Labs' briefing in this matter, explains why each and every one of the four Cort factors supports the existence of an implied private cause of action in CARES Act § 3202(a).

Second, the court reasoned that plaintiff in Murphy Medical decision failed to identify "anything in the text or structure of the CARES Act which suggests that Congress intended to afford them with a privately enforceable remedy." By comparison, Plaintiff has identified in extensive detail why the text and structure of the CARES Act shows that Congress intended to provide a privately enforceable reimbursement remedy in favor of diagnostic testing providers.

Third, Plaintiff in the Murphy Medical case argued primarily that "Congress's silence was merely a product of its rush to create legislation in the midst of the pandemic." Here, by contrast, Plaintiff has advanced numerous facts showing the text, purpose, legislative history, and historical Congressional action in this area of interstate concern all support finding a private cause of action. Indeed, in deciding Murphy Medical, the court appears to have couched its holding by implying plaintiff in that case may have been able to successfully plead "factual allegations demonstrating that the FFCRA and CARES Act incorporate[s] a private right of action." That is exactly what Plaintiff has done in pleading its claim in this case.

Lastly, the Murphy Medical court observed, without actually deciding, that the plaintiff testing provider before it may not be "remediless" because the Secretaries of Labor, Health and Human Services, and the Treasury suggested in FAQs, Part 43 that their Departments would enforce the FFCRA and CARES Act in conjunction with states. However, the mere suggestion that state or federal agencies might one day attempt to enforce CARES Act § 3202(a) of their own volition does not change the fact that Congress did not authorize them to do so, and that state and federal agencies have in fact not attempted to do so.

In contrast, the Court in *Diagnostic Affiliates* came to the same conclusions, reasoning the third *Cort* factor favors finding an implied private cause of action for violations of § 3202(a):

As discussed, Congress wanted widespread COVID-19 testing, which could only be accomplished by private entities quickly incurring the cost of establishing testing sites across the country and procuring the necessary supplies to administer tests. Legislative impatience with the finer points of the relationship between providers and insurance companies to properly allocate those costs or to determine appropriate pricing is evidenced by the inclusion of a mandatory methodology for determining the rate to be paid, if the parties did not have the time or cooperation to negotiate rates. A private right of action to recover the mandated reimbursement is fully consistent with the legislative scheme. 2022 WL 214101, at *9 (emphasis added). The Texas Court fully analyzed the availability of a private cause of action under the relevant part of the CARES Act. The Texas Court held that there is an implied private cause of action for violations of the Covid testing provisions in its ruling in Diagnostic Affiliates. In doing so, the court found that the cases cited by Defendants failed to address whether the FFCRA or CARES Act contains an implied right of action in favor of a COVID-19 testing provider seeking statutorilymandated reimbursements. The Court found that the cases did not contain any analogous fact patterns that would make their conclusions persuasive.

By proceeding directly to the question of an implied right of action, Diagnostic Affiliates concedes that the Acts do not create an express private right of action to enforce their provisions. D.E. 99, p. 10. So, the question is whether the terms of the legislation support the conclusion that there is an implied private right of action. San Juan Cable LLC v. P. R. Tel. Co., Inc., 612 F.3d 25, 29 (1st Cir. 2010); see also Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Curran, 456 U.S. 353, 378-88 (1982) (describing the analysis of whether a statute includes an implied private right of action as a matter of the legal context in which the statute was passed); Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 843 n.9 (1984) (statutory construction and legislative intent are matters of law).

2. Health Care Providers Have An Implied Private Right Of Action for Private Remedy Under The CARES Act.

The question of whether a federal statute contains an implied private right of action is "basically a matter of statutory construction." *Transamerica Mortg. Advisors, Inc. (TAMA) v. Lewis*, 444 U.S. 11, 15 (1979). The Supreme Court has enumerated several factors relevant to this analysis, as set forth in *Cort*, 422 U.S. at 78. *Id.* See, *Republic of Iraq v. ABB AG*, 768 F.3d 145, 170 (2d Cir. 2014) ("To 'illuminate' this analysis, we also consider factors enumerated in *Cort v. Ash*") (internal citation omitted)); see also *M.F. v. State of New York Exec. Dep't Div. of Parole*, 640 F.3d 491, 495 (2d Cir. 2011) (courts in the Second Circuit continue to apply the factors set forth in *Cort* in order to discern congressional intent to provide a private right of action); *Lindsay v. Ass'n of Prof'l Flight Attendants*, 581 F.3d 47, 52 n.3 (2d Cir. 2009) (same).

The CARES Act plainly create a benefit for the class of persons of which the Petitioner is a member: out-of-network providers who furnish COVID testing. The statute straightforwardly directs insurers like Aetna to pay out-of-network providers who furnish COVID-19 testing. Importantly, the statutes go further, describing how the amount such providers must be paid will be calculated. It states that "such plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website..." This provision "grant[s] private rights to members of an identifiable class." Transamerica Mortg. Advisors, Inc. (TAMA) v. Lewis, 444 U.S. at 24 Id. But the language used in the Cares Act reflects a legislative intent that is in fact consistent with providing a private right of action because Congress specifically identified a discrete group and then used language giving that group a right to reimbursement. Therefore, if such group is denied the right granted to it by Congress, they will have a remedy. In fact, one example of the difficulties caused by the rushed adoption of the CARES Act was the failure of Congress to provide a reimbursement calculation method for the time period where a provider had yet to publish their cash price on the website. Most providers such as the Petitioner, were in the early stages of the pandemic and scrambled to line up staff, equipment, and supplies to safely and effectively address the pandemic. The relevant CARES Act provisions are silent about what happens prior to any cash price being listed on the web site.

Clearly, Part II, Subpart A, Section 3201 of the CARES Act created a private cause of action for out-of-network providers of COVID-19 related testing and services, so as to prevent medical providers from directly

billing the patients. This was ensured via the text that all providers both in and out of network would receive full reimbursement in the absence of a negotiated rate. Moreover, if there were no private right of action, patients and medical providers would be left remediless, which is inappropriate. See, *Franklin v. Gwinnett County Pub. Schs.*, 503 U.S. 60, 76 (1992) (Finding private right of action for money damages under Title IX because administrative process would leave complainant "remediless").

Aetna argued that the CARES Act contains no statutory language focused on protecting private rights. Aetna's argument is simply inaccurate. As described above, Section 3201, protects the rights of reimbursement for out-of-network providers who rendered COVID testing services during the pandemic. As the Second Circuit has explained, when concluding that, "the provision of other (private or public) enforcement mechanisms (Bellikoff factors (i) and (ii)) merely "suggests" "that Congress intended to preclude" implied private rights of action." Oxford Univ. Bankv. Lansuppe Feeder, LLC, 933 F.3d 99, 106(2d Cir. 2019) (citing Alexander v. Sandoval, 532 U.S. 275, 290). Here, as in Oxford Univ. that "suggestion" is not particularly persuasive. The federal agencies are only empowered to fine Aetna for non-compliance. They are not empowered to protect the very specific right that Petitioner seeks to vindicate as their right to payment for services provided.

a. The CARES Act

The FFCRA and the CARES Act were passed in response to the public health emergency declared under Section 319 of the Public Health Service Act.

The purpose of including Section 6601 of the FFCRA and Section 3202(a) of the CARES Act was to two-fold: (1) to motivate and to provide reasonable assurances to providers capable of providing Covid Testing services that they would be reimbursed for the Covid Testing services it rendered throughout the course of the public health emergency; and (2) to provide reasonable assurances to members of health plans that they would not be held personally financially responsible for Covid Testing services as it would disincentive persons from being tested, in turn, further exacerbating the pandemic. This conscious decision by Congress to eliminate the patient from the reimbursement chain in out-of-network Covid Testing situations obviates the ordinary requirement for such provider to obtain a valid assignment, and, in the event there is an anti-assignment provision in the terms of the health plan- which there usually is - to obtain a validly executed and notarized special power of attorney.

The departments read the requirement to provide coverage without cost sharing in section 6001 of the FFCRA together with section 3202(a) of the CARES Act establishing a process for setting reimbursement rates, as intended to protect participants, beneficiaries, and enrollees from being balance billed for an applicable COVID 19 test. Section 3202(a) contemplates that a provider of COVID 19 testing will be reimbursed either a negotiated rate or an amount that equals the cash price for such service that is listed by the provider on a public website. Aetna's refusal to fully reimburse Petitioner illegally countermands Congress's directive to insurers to reimburse COVID-19 Diagnostic Testing Providers.

b. Congress Sought to Rapidly Increase Access to COVID-19 Testing Creating a Reimbursement Right Without Written Remedy Favoring An Implied Right Consistent with the Purpose of the CARES Act.

The second Cort factor is whether Congress manifested an intent to create an implied private right of action. This factor favors finding such an intention here because Congress did not enact any mechanism to enforce its mandate in § 3202(a). The Supreme Court has long held that when Congress enacts statutory provisions "stated in the form of commands," but for which "there is no mode of enforcement other than resort to the courts," courts have the "jurisdiction and duty to afford a remedy for a breach of statutory duty." Steele v. Louisville & N.R. Co., 323 U.S. 192, 207 (1944). Otherwise, the "right would be sacrificed or obliterated if it were without the remedy which courts can give for breach of such a duty or obligation." Id. The Supreme Court has reaffirmed this several times. Janus v. Am. Fed'n of State, Cty., & Mun. Emps., Council 31, 138 S. Ct. 2448, 2468 (2018); Int'l Bhd. of Elec. Workers v. Foust, 442 U.S. 42, 47 (1979); Cannon, (1979) 441 U.S. 677 at 693 n.13; Graham v. Bhd. of Locomotive Firemen & Enginemen, 338 U.S. 232, 239 (1949). Steele applies when the statute at issue contains a command (e.g., "shall reimburse"), but provides no enforcement mechanism.

The third *Cort* factor is whether an implied private cause of action is consistent with the purpose of the statute at issue. Here, a holding that providers of diagnostic testing have a right to obtain denied reimbursement from insurers is not only consistent with the plain and unambiguous

intention of Congress as expressed in § 3202(a) of the CARES Act, but it is also the only interpretation that is consistent with the underlying purpose of Act to rapidly increase access to COVID-19 testing.

It would completely defy Congress's objective to increase testing capacity and accessibility if there were no mechanism whatsoever to enforce the requirement that insurers reimburse providers for testing services at this critical time. The strong legislative resolve to increase the development of, and accessibility to, testing facilities requires there be a remedy for reimbursement to ensure the start-up and continued implementation of that legislative purpose when insurers unlawfully withhold reimbursement.

As the Supreme Court stated in *Cort*: "in situations in which it is clear that federal law has granted a class of persons certain rights, it is not necessary to show an intention to create a private cause of action, although an explicit purpose to <u>deny such cause of action</u> would be controlling." *Cort*, 422 U.S. at 82 (emphasis added). Thus, even if legislators did not express an intention to create a private cause of action, that does not prevent or deter finding that an implied private cause of action for reimbursement is consistent with the purposes of the CARES Act.

In *Cort*, the Court also explained that the maxim of *expressio unius est exclusio alterius* does not apply when there was no discussion whatever in Congress concerning private enforcement." *Id.* at 82 n.14. Here, there was no discussion in Congress concerning private enforcement; Congress was concerned more with

the pressing matters of an escalating pandemic. Thus, the rule that "[t]he express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others," *Alexander*, 532 U.S. at 290, has no application to this case. Based upon the foregoing, it should be found that an implied Congressional private right of actions exists under the CARES Act.

XIII. CONCLUSION

The petition for writ of certiorari should be granted.

Respectfully submitted,

MICHAEL L. GABRIEL, Esq. Counsel of Record 1903 A Cooley Avenue East Palo Altos, CA 94303 (650) 888-9189 aetal@earthlink.net

Counsel for Petitioner



APPENDIX A — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, FILED JUNE 23, 2022

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA

Case Nos. 22-cv-01696-JSC 22-cv-01702-JSC 22-cv-01703-JSC 22-cv-01704-JSC 22-cv-01706-JSC

SALOOJAS, INC.,

Plaintiff,

v.

AETNA HEALTH OF CALIFORNIA, INC.,

Defendant.

June 23, 2022, Decided June 23, 2022, Filed

ORDER RE: MOTIONS TO DISMISS

Plaintiff, a healthcare provider, brings five related cases against an insurer for underpaying for COVID

testing of five patients.¹ Before the Court are Defendant's identical motions to dismiss each of the five cases. (Case No. 22-cv-01696-JSC, Dkt. Nos. 5, 7, 14, 17, 19, 20; Case No. 22-cv-01702-JSC, Dkt. Nos. 7, 14, 18, 20, 21; Case No. 22-cv-01703-JSC, Dkt. Nos. 5, 11, 15, 17, 18; Case No. 22-cv-01704-JSC, Dkt. Nos. 6, 12, 16, 18, 19; Case No. 22-cv-01706-JSC, Dkt. Nos. 7, 14, 18, 20, 21.)² After carefully considering the parties' initial and supplemental briefing, (see Dkt. No. 18), the Court concludes that oral argument is unnecessary, see N.D. Cal. Civ. L.R. 7-1(b), and GRANTS the motions as explained below.

BACKGROUND

Plaintiff alleges Defendant underpaid for COVID tests that Plaintiff provided to Defendant's insureds between November 20 and 23, 2020. Plaintiff is outside of Defendant's provider network. It alleges that under Section 3202(a)(2) of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Defendant must "pay the entire bill at posted prices without any deductions"

 $^{1.\ (}See\ Case\ No.\ 22-cv-01696-JSC,\ Dkt.\ No.\ 1\ at\ 6\ ("Patient\ ID\ no:\ 2069047");\ Case\ No.\ 22-cv-01702-JSC,\ Dkt.\ No.\ 1\ at\ 6\ ("Patient\ ID\ no:\ 2068896");\ Case\ No.\ 22-cv-01703-JSC,\ Dkt.\ No.\ 1\ at\ 6\ ("Patient\ ID\ no:\ 2068125");\ Case\ No.\ 22-cv-01704-JSC,\ Dkt.\ No.\ 1-1\ at\ 3\ ("Patient\ ID\ no:\ 2068239");\ Case\ No.\ 22-cv-01706-JSC,\ Dkt.\ No.\ 1\ at\ 6\ ("Patient\ ID\ no:\ 2069003").)\ A\ sixth\ related\ case\ does\ not\ have\ a\ pending\ motion\ to\ dismiss.\ (Case\ No.\ 22-cv-02887-JSC.)$

^{2.} Record citations are to material in the Electronic Case File ("ECF") for Case No. 22-cv-01696-JSC, unless otherwise indicated; pinpoint citations are to the ECF-generated page numbers at the top of the documents.

for cop[a]y or deductibles." (Dkt. No. 1 at 7.) For the five patients at issue, Plaintiff contends Defendant owes \$922, \$1,090, \$1,090, \$924, and \$922, each rounded up to \$2,500 to account for a "balance" of "punitive damages . . . for intentional violation" of the CARES Act. (*Id.* at 6.)³

Plaintiff filed in small claims court in Alameda County. It attached as an exhibit an undated letter from Plaintiff to Defendant, on letterhead of AFC Urgent Care of Newark, appealing Defendant's payment decision and asserting that the CARES Act requires Defendant to pay Plaintiff's posted cash prices. (*Id.* at 12-15.) For two cases, Plaintiff attached October 2021 letters from Defendant to Plaintiff, each denying an appeal request because it was filed after the 60-day deadline. (*Id.* at 16-17; Case No. 22-cv-01703-JSC, Dkt. No. 1 at 16.) For the other three cases, Plaintiff attached an acknowledgement of appeal request, an acknowledgement of dispute, and an appeal denial, respectively. (Case No. 22-cv-01702-JSC, Dkt. No. 1 at 17; Case No. 22-cv-01704-JSC, Dkt. No. 1-1 at 13; Case No. 22-cv-01706-JSC, Dkt. No. 1 at 12.)

Thereafter, Defendant removed to federal court. Defendant moves to dismiss for failure to state a claim, *see* Fed. R. Civ. P. 12(b)(6), on the grounds that the CARES

^{3. (}See Case No. 22-cv-01702-JSC, Dkt. No. 1 at 6; Case No. 22-cv-01703-JSC, Dkt. No. 1 at 6; Case No. 22-cv-01704-JSC, Dkt. No. 1-1 at 3; Case No. 22-cv-01706-JSC, Dkt. No. 1 at 6.)

^{4.} The Court takes judicial notice of these documents attached to the complaints. *See Parks Sch. of Bus., Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995).

Act does not provide a private right of action to Plaintiff.

DISCUSSION

Section 3202 of the CARES Act provides:

PRICING OF DIAGNOSTIC TESTING.

- (a) REIMBURSEMENT RATES.—A group health plan or a health insurance issuer providing coverage of items and services described in section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116-127) with respect to an enrollee shall reimburse the provider of the diagnostic testing as follows:
- (1) If the health plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), such negotiated rate shall apply throughout the period of such declaration.
- (2) If the health plan or issuer does not have a negotiated rate with such provider, such plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or such plan or issuer may negotiate a rate with such provider for less than such cash price.

- (b) REQUIREMENT TO PUBLICIZE CASH PRICE FOR DIAGNOSTIC TESTING FOR COVID-19.—
- (1) IN GENERAL.—During the emergency period declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), each provider of a diagnostic test for COVID-19 shall make public the cash price for such test on a public internet website of such provider.
- (2) CIVIL MONETARY PENALTIES.—The Secretary of Health and Human Services may impose a civil monetary penalty on any provider of a diagnostic test for COVID-19 that is not in compliance with paragraph (1) and has not completed a corrective action plan to comply with the requirements of such paragraph, in an amount not to exceed \$300 per day that the violation is ongoing.

Pub. L. 116-136, § 3202 (Mar. 27, 2020), 134 Stat. 367. Thus, Section 3202 referenced and amended Section 6001(a) of the Families First Coronavirus Response Act ("FFCRA"). See id. § 3201; Pub. L. 116-127, § 6001(a) (Mar. 18, 2020), 134 Stat. 178. Section 6001, in turn, provides:

COVERAGE OF TESTING FOR COVID-19.

(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage . . . shall

provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) beginning on or after the date of the enactment of this Act:

- (1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products.
- (2) Items and services furnished to an individual during health care provider office visits (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of

determining the need of such individual for such product.

- (b) ENFORCEMENT.—The provisions of subsection (a) shall be applied by the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury to group health plans and health insurance issuers offering group or individual health insurance coverage as if included in the provisions of part A of title XXVII of the Public Health Service Act, part 7 of the Employee Retirement Income Security Act of 1974, and subchapter B of chapter 100 of the Internal Revenue Code of 1986, as applicable.
- (c) IMPLEMENTATION.—The Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury may implement the provisions of this section through sub-regulatory guidance, program instruction or otherwise.
- (d) TERMS.—The terms "group health plan"; "health insurance issuer"; "group health insurance coverage", and "individual health insurance coverage" have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91), section 733 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Code of 1986, as applicable.

Pub. L. 116-127, § 6001. Plaintiff bases its claim on CARES Act Section 3202(a)(2)'s directive that an insurer "shall reimburse" the provider at "the cash price" of testing if the insurer "does not have a negotiated rate" with the provider. Pub. L. 116-136, § 3202(a). Plaintiff concedes that the CARES Act provides no express right of action for its testing reimbursement claim, but argues there is an implied right of action.

"Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Alexander v. Sandoval*, 532 U.S. 275, 286, 121 S. Ct. 1511, 149 L. Ed. 2d 517 (2001). The Supreme Court's opinions in *Cort* and *Alexander* govern whether a statute implies a private right of action. *Id.*; *Cort v. Ash*, 422 U.S. 66, 95 S. Ct. 2080, 45 L. Ed. 2d 26 (1975); *see McGreevey v. PHH Mortg. Corp.*, 897 F.3d 1037, 1043-44 (9th Cir. 2018). *Cort* lays out four factors:

First, is the plaintiff one of the class for whose especial benefit the statute was enacted—that is, does the statute create a federal right in favor of the plaintiff? Second, is there any indication of legislative intent, explicit or implicit, either to create such a remedy or to deny one? Third, is it consistent with the underlying purposes of the legislative scheme to imply such a remedy for the plaintiff? And finally, is the cause of action one traditionally relegated to state law, in an area basically the concern of the States, so that it would be inappropriate to infer a cause of action based solely on federal law?

422 U.S. at 78 (cleaned up). The Ninth Circuit has explained that the Cort factors "remain relevant," but "the focus now is on" Alexander. McGreevey, 897 F.3d at 1043. Alexander asks "whether Congress displays through the statute an intent to create not just a private right but also a private remedy. Statutory intent . . . is determinative; without Congress's intent to create a remedy, no right of action can be implied." Id. at 1043-44 (cleaned up); see also Touche Ross & Co. v. Redington, 442 U.S. 560, 575, 99 S. Ct. 2479, 61 L. Ed. 2d 82 (1979) ("[Cort] did not decide that each of these factors is entitled to equal weight. The central inquiry remains whether Congress intended to create, either expressly or by implication, a private cause of action."). Courts "begin . . . [the] search for Congress's intent with the text and structure of" the statute. Alexander, 532 U.S. at 288.

The Court is aware of only two cases that have addressed whether an implied right of action exists for a testing reimbursement claim under the CARES Act. See Murphy Med. Assocs., LLC v. Cigna Health & Life Ins. Co., No. 3:20cv1675(JBA), 2022 U.S. Dist. LEXIS 43351, 2022 WL 743088, at *2-6 (D. Conn. Mar. 11, 2022) (no); Diagnostic Affiliates of Northeast Hou v. United Healthcare Servs, No. 2:21-CV-00131, 2022 U.S. Dist. LEXIS 14132, 2022 WL 214101, at *4-9 (S.D. Tex. Jan. 18, 2022) (yes).

A. Text and Structure of the CARES Act

The text and structure of the CARES Act do not show congressional intent to create a private right of action

for COVID-19 test providers like Plaintiff. The CARES Act creates rights and duties for providers: in Section 3202(a), the right to reimbursement of the published cash price from an insurer who does not have a negotiated rate, and in Section 3202(b), the duty to publish a cash price. Section 3202(a), the substantive basis for Plaintiff's claim, has no enforcement language. Pub. L. 116-136, § 3202(a). Section 3202(b) provides that the Secretary of Health and Human Services "may impose a civil monetary penalty on any provider of a diagnostic test... that is not in compliance with" the requirement to publish a cash price. *Id.* § 3202(b). Thus, Section 3202 only contemplates enforcement against providers, not against insurers who fail to reimburse providers, and only administrative enforcement, not a private right of action.

For its part, FFCRA Section 6001 provides that the Secretaries of Health and Human Services, Labor, and the Treasury may enforce Section 6001(a) against "group health plans and health insurance issuers." Pub. L. 116-127, § 6001(b); see Pub. L. 116-136, § 3202(a) (referencing FFCRA Section 6001(a)). Assuming without deciding that FFCRA Section 6001 allows the Secretaries to enforce CARES Act Section 3202(a) against insurers, that would not show congressional intent to create a private right of action for providers like Plaintiff to enforce the provision against insurers. See Alexander, 532 U.S. at 289 ("Nor do the methods that § 602 goes on to provide for enforcing its authorized regulations manifest an intent to create a private remedy; if anything, they suggest the opposite."); see also Murphy Med. Assocs., LLC, 2022 U.S. Dist. LEXIS 43351, 2022 WL 743088, at *5 n.5 (noting

Secretaries' joint Frequently Asked Questions document and ambiguity regarding administrative enforcement scheme).

In its supplemental brief, Plaintiff argues that it is separately entitled to challenge Defendant's reimbursement through private rights of action created by the Employee Retirement Income Security Act ("ERISA"). (Dkt. No. 20.) This argument fails because nothing in Plaintiff's complaint references ERISA. The small claims complaint states, "COVID TESTING SERVICE[S] under the CARES ACT were rendered Insurance company owes \$922 and the balance is punitive damages to \$2,500 for the intentional violation of the Federal CARES ACT." (Dkt. No. 1 at 6.) "[U]nder the CARES ACT sec 3202(a) (2)[,] Defendants are required to pay the entire bill at posted prices Plaintiff appealed the denial of full payment mandated under the CARES ACT " (Id. at 7.) Thus, the complaint does not "give the defendant fair notice" that ERISA provides "the grounds upon which" Plaintiff's claim rests. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (cleaned up). CARES Act Section 3202(a)'s reference to FFCRA Section 6001, which in turn refers to ERISA, is too removed to provide notice that Plaintiff's claim rests on an ERISA private right of action. See Pub. L. 116-136, § 3202(a); Pub. L. 116-127, § 6001(b), (d).

B. Cort Factors

Turning to the *Cort* factors, to the extent they "remain relevant," *McGreevey*, 897 F.3d at 1043, three

factors weigh in favor of an implied private right of action but the most important factor does not. *See Touche Ross*, 442 U.S. at 575 ("[*Cort*] did not decide that each of these factors is entitled to equal weight.").

First, the CARES Act "create[s] a federal right in favor of" Plaintiff: the right to reimbursement at the posted cash price. Cort, 422 U.S. at 78; see Pub. L. 116-136, § 3202(a)(2). Third, it is "consistent with the underlying purposes of the legislative scheme to imply such a remedy." Cort, 422 U.S. at 78. The purpose of this part of the CARES Act scheme is to incentivize healthcare organizations to provide COVID-19 testing and to make testing widely available to prevent the spread of COVID-19. See Diagnostic Affiliates of Northeast Hou, 2022 U.S. Dist. LEXIS 14132, 2022 WL 214101, at *6 ("[T]he legislative objective was to ensure that COVID-19 testing was widely available to the entire population."), *9 ("Congress wanted widespread COVID-19 testing, which could only be accomplished by private entities quickly incurring the cost of establishing testing sites across the country and procuring the necessary supplies to administer tests."). Fourth, a cause of action for diagnostic testing reimbursement, particularly with respect to the global pandemic, is not "traditionally relegated to state law" or "in an area basically the concern of the States." Cort, 422 U.S. at 78.

The second, most important factor echoes *Alexander* in considering whether there is "any indication of legislative intent, explicit or implicit, either to create such a remedy or to deny one." *Id.* As explained above, there

is no indication of implicit intent to create such a remedy and Plaintiff concedes there is no indication of explicit intent. Although there is no indication of intent to deny a remedy, see Diagnostic Affiliates, 2022 U.S. Dist. LEXIS 14132, 2022 WL 214101, at *8, that is not enough to imply one. See McGreevey, 897 F.3d at 1043-44; Murphy Med., 2022 U.S. Dist. LEXIS 43351, 2022 WL 743088, at *5 ("[I] f Congress has manifested no intent to provide a private right of action, the Court cannot create one." (cleaned up)).

The district court's opinion in Diagnostic Affiliates does not persuade the Court otherwise. On the most important Cort factor and the primary inquiry under Alexander, the court concluded that "the administrative enforcement scheme cannot be said to evidence an intent to deny a private right of action." 2022 U.S. Dist. LEXIS 14132, 2022 WL 214101, at *8. "[C]lear rights to reimbursement were created and no other enforcement mechanism exists. An implied private right of action is a more appropriate construction of the statute than the creation of a right without any remedy." Id. This reasoning does not square with the Supreme Court's directive in Alexander: "The judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy. Statutory intent on this latter point is determinative." 532 U.S. at 286 (citation omitted). Thus, the reasoning in the other district court case, Murphy *Medical*, is more persuasive. 2022 U.S. Dist. LEXIS 43351, 2022 WL 743088, at *2-6.

* * *

The CARES Act does not provide an implied private right of action for Plaintiff to seek reimbursement of its posted cash price. Accordingly, Plaintiff's complaint does not state a claim on which relief could be granted. See Johnson v. Riverside Healthcare Sys., 534 F.3d 1116, 1121 (9th Cir. 2008) (noting that dismissal under Rule 12(b) (6) "may be based on either a lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory" (cleaned up)).

Although amendment of a CARES Act claim would be futile, Plaintiff argues that it could amend its complaint to state a claim under ERISA. Without the benefit of full briefing, the Court cannot conclude that such claim would fail as a matter of law. Accordingly, leave to amend is proper. *See Yagman v. Garcetti*, 852 F.3d 859, 863 (9th Cir. 2017).

CONCLUSION

Defendant's motions to dismiss are GRANTED. Plaintiff may file amended complaints that assert claims under ERISA on or before **July 25, 2022**.

This Order disposes of Docket No. 5 in Case No. 22-cv-01696-JSC; Docket No. 7 in Case No. 22-cv-01702-JSC; Docket No. 5 in Case No. 22-cv-01703-JSC; Docket No. 6 in Case No. 22-cv-01704-JSC; and Docket No. 7 in Case No. 22-cv-01706-JSC.

15a

$Appendix\,A$

IT IS SO ORDERED.

Dated: June 23, 2022

/s/ Jacqueline Scott Corley JACQUELINE SCOTT CORLEY United States District Judge

APPENDIX B — RELEVANT STATUTORY PROVISIONS

THE CORONAVIRUS AID, RELIEF AND ECONOMIC SECURITY ("CARES") ACT

H.R. 748 PUB. L. NO. 116-136

PART II—ACCESS TO HEALTH CARE FOR COVID-19 PATIENTS Subpart A—Coverage of Testing and Preventive Services

SEC. 3201. COVERAGE OF DIAGNOSTIC TESTING FOR COVID-19. Paragraph (1) of section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116–127) is amended to read as follows: "

- (1) An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, and the administration of such a test, that—
 - "(A) is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb-3);
 - "(B) the developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), unless

and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable time frame;

- "(C) is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID 19; or
- "(D) other test that the Secretary determines appropriate in guidance.".

SEC. 3202. PRICING OF DIAGNOSTIC TESTING.

- (a) **REIMBURSEMENT RATES.**—A group health plan or a health insurance issuer providing coverage of items and services described in section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116–127) with respect to an enrollee shall reimburse the provider of the diagnostic testing as follows:
 - (1) If the health plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), such negotiated rate shall apply throughout the period of such declaration.

(2) If the health plan or issuer does not have a negotiated rate with such provider, such plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or such plan or issuer may negotiate a rate with such provider for less than such cash price.

(b) REQUIREMENT TO PUBLICIZE CASH PRICE FOR DIAGNOSTIC TESTING FOR COVID-19.

- (1) IN GENERAL.—During the emergency period declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), each provider of a diagnostic test for COVID–19 shall make public the cash price for such test on a public internet website of such provider.
- (2) CIVIL MONETARY PENALTIES.—The Secretary of Health and Human Services may impose a civil monetary penalty on any provider of a diagnostic test for COVID-19 that is not in compliance with paragraph (1) and has not completed a corrective action plan to comply with the requirements of such paragraph, in an amount not to exceed \$300 per day that the violation is ongoing.

SEC. 3203. RAPID COVERAGE OF PREVENTIVE SERVICES AND VACCINES FOR CORONAVIRUS.

(a) IN GENERAL.—Notwithstanding 2713(b) of the Public Health Service Act (42 U.S.C. 300gg-13), the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall require group health plans and health insurance issuers offering group or individual health insurance to cover (without costsharing) any qualifying coronavirus preventive service, pursuant to section 2713(a) of the Public Health Service Act (42 U.S.C. 300gg-13(a)) (including the regulations under sections 2590.715–2713 of title 29, Code of Federal Regulations, section 54.9815-2713 of title 26, Code of Federal Regulations, and section 147.130 of title 45, Code of Federal Regulations (or any successor regulations)). The requirement described in this subsection shall take effect with respect to a qualifying coronavirus preventive service on the specified date described in subsection (b)(2).

(b) DEFINITIONS.—For purposes of this section:

- (1) QUALIFYING CORONAVIRUS PREVENTIVE SERVICE.—The term "qualifying coronavirus preventive service" means an item, H. R. 748—88 service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 and that is—
 - (A) an evidence-based item or service that has in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force; or

- (B) an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.
- (2) **SPECIFIED DATE**.—The term "specified date" means the date that is 15 business days after the date on which a recommendation is made relating to the qualifying coronavirus preventive service as described in such paragraph.
- (3) **ADDITIONAL TERMS.**—In this section, the terms "group health plan", "health insurance issuer", "group health insurance coverage", and "individual health insurance coverage" have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), section 733 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Code, as applicable.

FAMILIES FIRST CORONAVIRUS RESPONSE ACT ("FFRCA") PUB. L. NO. 116-1127 (2020)

DIVISION F—HEALTH PROVISIONS

SEC. 6001. COVERAGE OF TESTING FOR COVID-19.

- (a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan (as defined in section 1251(e) of the Patient Protection and Affordable Care Act)) shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b–5(g)) beginning on or after the date of the enactment of this Act:
 - (1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products.
 - (2) Items and services furnished to an individual during health care provider office visits (which

term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.

- (b) ENFORCEMENT.—The provisions of subsection (a) shall be applied by the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury to group health plans and health insurance issuers offering group or individual health insurance coverage as if included in the provisions of part A oftitle XXVII of the Public Health Service Act, part 7 of the Employee Retirement Income Security Act of 1974, and subchapter B of chapter 100 of the Internal Revenue Code of 1986, as applicable.
- (c) IMPLEMENTATION.—The Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury mayimplement the provisions of this section through sub-regulatoryguidance, program instruction or otherwise.
- (d) TERMS.—The terms "group health plan"; "health insurance issuer"; "group health insurance coverage", and "individual health insurance coverage" have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91), section 733 of the

23a

$Appendix\,B$

Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Codeof 1986, as applicable.