UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

GS LABS, LLC, a Nebraska limited liability company,) Case No.: 21-cv-2400 (SRN/TNL)
Plaintiff,)
) PLAINTIFF'S MOTION FOR
v.) PARTIAL SUMMARY
	JUDGMENT
MEDICA INSURANCE COMPANY, a)
Minnesota insurance corporation,)
)
Defendant.)
)

Pursuant to Fed. R. Civ. P. 56, Plaintiff GS Labs, LLC ("GS Labs"), hereby moves the Court for an Order granting GS Labs partial summary judgment on Count II of its Complaint. GS Labs' motion will be based upon the file, record, and pleadings being served and filed concurrently herewith, and the arguments of counsel.

Dated: November 12, 2021 WINTHROP & WEINSTINE, P.A.

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UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

GS LABS, LLC, a Nebraska limited liability company,) Case No.: 21-cv-2400 (SRN/TNL)
Plaintiff,))
) PLAINTIFF'S MEMORANDUM
V.) IN SUPPORT OF ITS MOTION
) FOR PARTIAL SUMMARY
MEDICA INSURANCE COMPANY, a	JUDGMENT
Minnesota insurance corporation,)
)
Defendant.)
)

This is an action seeking full reimbursement for the publicly-posted cash price of lifesaving COVID-19 diagnostic testing that Plaintiff GS Labs, LLC ("GS Labs") provided to over 16,000 insureds of Defendant Medica Insurance Company's ("Medica"). GS Labs provided this testing to urgently respond to the federally-established policy and law enacted by Congress to address the crippling worldwide COVID-19 pandemic, which has now claimed over 750,000 American lives. Medica has refused to fully reimburse GS Labs, as plainly required by federal law.

GS Labs respectfully requests the Court enter summary judgment on two pure questions of law, raised in GS Labs' Count II for Declaratory Judgment, which are at the heart of the parties' dispute: (1) that the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") requires Medica to fully reimburse GS Labs at the publicly-posted cash price for COVID-19 diagnostic testing; and (2) that GS Labs has an implied private cause of action under the CARES Act to recover that reimbursement from Medica.

The Court should answer the first question in the affirmative: The CARES Act uses clear language directing that a "health plan issuer" (i.e., insurance company) like Medica "shall reimburse the provider of the diagnostic testing." CARES Act § 3202(a) (emphasis added). The CARES Act establishes the reimbursement rates for this testing shall be either: (1) the "negotiated rate" with a provider, if the insurer had negotiated a rate with the provider "before the public health emergency" of the COVID-19 pandemic; or, if there was no such pre-pandemic negotiated rate for testing, then (2) "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." *Id.* Medica did not negotiate an alternative rate with GS Labs before the pandemic began. And Medica still has not agreed to a negotiated rate with GS Labs. Therefore, the Court should declare that under the CARES Act, the reimbursement rate "equals the cash price for such service as listed by the provider on a public internet website," i.e., the cash prices GS Labs posted on its public website are the reimbursement rates under § 3202(a).

The Court should also answer the second question in the affirmative: The CARES Act's express, directive language *and* its legislative history both demonstrate that Congress intended to provide a private cause of action to diagnostic testing providers, like GS Labs, to collect reimbursement for COVID-19 testing from insurers, like Medica, who refuse to comply with the law. The CARES Act requires that insurers "shall reimburse the provider

¹ Pub. L. No. 116-136, 134 Stat. 281 (2020), *available at*: https://www.govinfo.gov/app/details/PLAW-116publ136.

of the diagnostic testing." CARES Act § 3202(a) (emphasis added). In passing the CARES Act, Congress sought to act quickly to increase access to diagnostic testing to respond to COVID-19's high rates of infection and spread, and to eliminate economic barriers to receiving testing. Congress thus required that insurers reimburse all diagnostic testing providers at rates specified and made certain by law (i.e., publicly-posted cash prices or negotiated rates). The CARES Act does not provide for any administrative remedies if an insurer fails to reimburse at the applicable rate, and no agency has asserted authority to provide such a remedy. Accordingly, an implied cause of action both was contemplated and is necessary for GS Labs and other COVID-19 testing providers to have the legal recourse to enforce these express reimbursement obligations under the CARES Act. The language, structure, and history of the Act demonstrate Congress intended to imply a private cause of action for the benefit of diagnostic testing providers to recover reimbursement from insurers who refuse to pay as Congress directed.

Again, these are purely legal issues that divide the parties. The Court's rulings will focus this litigation. For these reasons and those further reasons below, GS Labs respectfully moves for summary judgment on its declaratory judgment claim in Count II.

BACKGROUND

The relief sought by GS Labs in this motion is based on undisputed material facts, and does not require the Court to decide any factual disputes. Accordingly, this section is solely intended to set out basic context regarding the parties' dispute.

A. GS Labs Has Administered COVID-19 Tests to Over 16,000 Medica Insureds.

GS Labs was formed in January 2020 as a clinical lab in Omaha, Nebraska. ("Declaration of Kirk Thompson ("Thompson Decl.") \P 2.) In response to the COVID-19 public health emergency in early 2020, GS Labs invested in and opened over 50 testing sites across the country. (*Id.* \P 3.) GS Labs did not negotiate a reimbursement rate with Medica for diagnostic testing in advance of the COVID-19 public health emergency that was declared in January 2020.² (*Id.* \P 4.)

GS Labs has provided COVID-19 diagnostic tests to over 16,000 patients who are Medica insureds. (Id. \P 8.) Medica has never disputed that the tests provided by GS Labs to Medica's insureds meet the definition of "diagnostic testing" under the CARES Act and Families First Coronavirus Response Act ("FFCRA"). (Id. \P 9.)

GS Labs provided COVID-19 diagnostic tests to Medica's insureds. (Id. ¶ 8.) Pursuant to the CARES Act, GS Labs has submitted requests for reimbursement to Medica based on the insurance information provided by the insureds to GS Labs. (Id. ¶ 10.)

B. Medica Refuses to Fully Reimburse GS Labs for Diagnostic Testing, in Violation of the Plain Terms of the CARES Act.

It is undisputed that Medica has withheld full reimbursement to GS Labs. (*Id.* ¶ 11.) Despite GS Labs' requests that Medica provide full reimbursement, Medica has refused to do so for almost an entire year. (*Id.* ¶ 12.) Nor has Medica agreed to any negotiated alternative price for GS Labs' diagnostic testing. (*Id.* ¶ 13.)

² See Determination that a Public Health Emergency Exists, U.S. Dep't Health & Human Servs. (Jan. 31, 2020),

https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

Accordingly, Medica's failure and refusal to reimburse GS Labs at the publicly-posted cash price for this COVID-19 diagnostic testing plainly violates the CARES Act.

STANDARD FOR REVIEW

"The [C]ourt shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party "bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If there is no genuine dispute, and the movant is entitled to judgment as a matter of law, then the Court "shall grant summary judgment." Fed. R. Civ. P. 56(a).

ARGUMENT

This motion is based on two undisputed facts: GS Labs provided COVID-19 diagnostic testing to Medica's insureds; and Medica has refused to fully reimburse GS Labs for this testing. Thus, there are no genuine disputes as to the facts necessary for the Court to decide the two questions of law presented by this motion. GS Labs is entitled to judgment that: (1) the CARES Act requires Medica to fully reimburse GS Labs at the publicly-posted cash price for COVID-19 diagnostic testing; and (2) GS Labs has an implied private cause of action under the CARES Act to recover that reimbursement from Medica.

I. The CARES Act Requires Medica to Fully Reimburse GS Labs at the Publicly-posted Cash Price for COVID-19 Diagnostic Testing.

The CARES Act requires Medica to fully reimburse GS Labs at the cash price listed on GS Labs' public internet site for the COVID-19 diagnostic testing that GS Labs has provided to over 16,000 of Medica's insureds.

Section 3202(a) of the CARES Act provides:

- (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 <u>shall reimburse</u> 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.

CARES Act § 3202(a) (emphasis added).

As stated, GS Labs has provided COVID-19 diagnostic tests to over 16,000 patients who are Medica insureds. (Thompson Decl. \P 8.) Medica has never disputed that the tests provided by GS Labs to Medica's insureds meet the definition of "diagnostic testing" under the CARES Act and FFCRA. (*Id.* \P 9.)

GS Labs and Medica did not agree to a negotiated rate for diagnostic testing prepandemic, nor have GS Labs and Medica agreed to a negotiated rate since the first public health emergency declaration in January 2020. (*Id.* ¶¶ 4, 13.) Therefore, Congress has directed that Medica "shall reimburse" GS Labs "in an amount that equals the cash price for such service as listed by the provider on a public internet website." CARES Act § 3202(a) (emphasis added). GS Labs is entitled to a declaration as to this straightforward application of law to the undisputed facts.

Medica cannot argue it is entitled to review COVID-19 testing reimbursement requests for medical appropriateness or necessity as a condition to reimbursement. Any such contention fails under the plain terms of both federal law and executive branch agency guidance. Along with the CARES Act, Congress enacted the FFCRA, which in § 6001(a) clearly states: "A group health plan and 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 [(diagnostic testing)]." Put simply, Congress has prohibited Medica from imposing conditions precedent to reimbursement. See Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26, 35 (1998) (observing that "shall" typically "creates an obligation impervious to . . . discretion").

In addition, the Departments of Labor, Health and Human Services, and Treasury have jointly issued "Frequently Asked Questions" guidance to provide direction regarding the FFCRA and CARES Act, and this guidance explains that insurers such as Medica may not "use medical screening criteria to deny (or impose cost sharing on) a claim for COVID-19 diagnostic testing," or "require the presence of symptoms or a recent known or

³ Pub. L. No. 116-127, 134 Stat. 177 (2020); *available at*: https://www.govinfo.gov/app/details/PLAW-116publ127.

suspected exposure, or otherwise impose medical screening criteria on coverage of tests."⁴ Thus, like Congress, each of these federal executive agencies prohibits Medica from imposing conditions precedent to reimbursement.

Therefore, there can be no genuine dispute that the CARES Act requires Medica to fully reimburse GS Labs for the COVID-19 diagnostic testing that GS Labs has provided to Medica's insureds, at the cash price listed on GS Labs' public internet site when GS Labs performed the testing. Accordingly, GS Labs respectfully requests the Court enter an order making this clear declaration that Medica has denied.

II. GS Labs Has an Implied Private Cause of Action Under the CARES Act to Recover Full Reimbursement from Medica at the Publicly-posted Cash Price.

The language, structure, and history of the CARES Act show that Congress intended to provide diagnostic testing providers, such as GS Labs, with a private cause of action against insurers to enforce the reimbursement rights that Congress created for the benefit of providers in § 3202(a). Indeed, it would be both illogical and unreasonable to hold that Congress created a reimbursement right for the benefit of providers such as GS Labs, but simultaneously intended there be no means for such providers who have the right to reimbursement to enforce that obligation and obtain that Congressionally-intended benefit. It would also be unjust to enable large insurers like Medica to skirt Congress's directive that it "shall reimburse" providers like GS Labs by holding there is no such cause of action.

⁴ FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44, at 1-3 (Feb. 26, 2021), https://www.cms.gov/files/document/faqs-part-44.pdf.

To determine whether an implied private remedy exists under a federal statute, the Court must "interpret the statute Congress . . . passed to determine whether it displays an intent to create . . . a private remedy." *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001). Statutory intent to create a private remedy "is determinative." *Id.* Congressional intent to create a federal private remedy is manifested by the inclusion of "rights creating" language. *Alexander*, 532 U.S. at 288 (quoting *Cannon v. Univ. of Chicago*, 441 U.S. 677, 693 n.13 (1979)). This analysis focuses on "the text and structure of" the relevant statute. *Id.*

In evaluating congressional intent, the Court considers four primary factors: (1) whether the plaintiff is a member of the class of persons for whose benefit the statute was enacted; (2) whether the legislature has implicitly or explicitly manifested any intent to create or deny such a remedy; (3) whether it is consistent with the underlying purpose of the legislative scheme to imply such a remedy; and (4) whether the cause of action is traditionally a creature of state law such that inferring a cause of action based solely on federal law would be inappropriate. *Cort v. Ash*, 422 U.S. 66, 78 (1975).

Applying these factors, the Supreme Court has held there are implied private causes of action in several realms, ranging from securities fraud under SEC Rule 10b-5, *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 730 (1975), to—most recently—civil rights, *Comcast Corp. v. Nat'l Ass'n of Afr. Am.-Owned Media*, 140 S. Ct. 1009, 1019 (2020). In these and additional areas, the Court has ruled that "unless and until Congress acts, the federal courts must fill in the interstices of the implied cause of action." *Merrill Lynch*, *Pierce, Fenner & Smith, Inc. v. Curran*, 456 U.S. 353, 394–95 (1982). So too here.

A. GS Labs Is a Member of the Class of Persons for Whose Benefit Congress Enacted § 3202(a) and Required Reimbursement.

First, GS Labs is a member of the class of persons for whose benefit Congress enacted the reimbursement right in § 3202(a) of the CARES Act.

In evaluating this first factor, courts review the statute to discern an "unmistakable focus on the benefited class," as distinguished from a general ban on conduct or expression of public policy. *Cannon*, 441 U.S. at 691. Courts also review the statute to determine if it contains "rights-creating language." *Alexander*, 532 U.S. at 288 (quoting *Cannon*, 441 U.S. at 693 n.13). For example, the Supreme Court has held that the provision "no person shall be subjected to discrimination" (brackets, ellipsis, and quotation omitted) is "rights-creating" language. *Alexander*, 332 U.S. at 288 (citing *Cannon*, 441 U.S. at 693).

Here, § 3202(a) uses "rights-creating language" that focuses on diagnostic testing providers, which evidences Congress' intent to create a private cause of action. Section 3202(a) not *once*, but *twice*, provides rights-creating language directing that insurers "shall reimburse" the class of persons who are diagnostic testing providers like GS Labs. First, at the outset, § 3202(a) provides that an insurer "shall reimburse the provider of the diagnostic testing." Second, in the event there was no pre-pandemic negotiated price between the insurer and "such provider," then the insurer "shall reimburse the provider" at "the cash price for such service as listed by the provider on a public internet website." Section 3202(a)'s repeated and emphatic use of the phrases "provider" and "shall reimburse" demonstrates Congress's clear intent to create a private right of action for the benefit of providers of diagnostic testing. See Transamerica Mortg. Advisors, Inc. v. Lewis,

444 U.S. 11, 19 (1979) ("[W]hen Congress declared . . . that certain contracts are void, *it intended that the customary legal incidents* of voidness *would follow*, including the availability of a suit for rescission or for an injunction against continued operation of the contract, and for restitution"); *see also Maine Com'y Health Options v. United States*, 140 S. Ct. 1308, 1320-21 (2020) (finding *insurers* had right to payment from federal Government based on mandatory statutory term "shall").

Put simply, Congress's use of the word "shall" in connection with "reimburse," and the statute's focus on providing reimbursement to the "provider of diagnostic testing," makes clear to all who read it that Congress intended to codify a right to reimbursement in favor of diagnostic testing providers like GS Labs. Indeed, this clear language can only have been intended for the benefit of diagnostic testing providers. Therefore, this factor "[u]nquestionably" supports finding a private right of action in favor of diagnostic testing providers. *Cannon*, 441 U.S. at 693.

B. Congress Manifested Its Intention to Create a Private Right of Action By Creating a Reimbursement Right with No Alternative Enforcement Mechanisms.

Second, Congress has both implicitly and explicitly manifested an intent to create a private reimbursement remedy for the benefit of providers of COVID-19 diagnostic testing, as shown by the absence of any other enforcement mechanisms under § 3202.

The CARES Act does not provide any alternate means of enforcing Section 3202(a)'s reimbursement right. *See* CARES Act §§ 3201-3203. 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.* Moreover, "where no enforcement mechanism is explicitly provided by Congress or an administrative agency, it is appropriate to infer that Congress did not intend to enact unenforceable requirements." *See First Pac. Bancorp, Inc. v. Helfer*, 224 F.3d 1117, 1126 (9th Cir. 2000) (emphasis added).

Notably, § 3202(b) deputizes the Secretary of Health and Human Services to "impose a civil monetary penalty on any *provider* of a diagnostic test for COVID–19 that is not in compliance with paragraph (1)" by failing to "make public the cash price for such test on a public internet website of such provider." CARES Act § 3202(b). But apart from this narrow enforcement mechanism requiring *providers* of diagnostic testing to list their cash prices on their public internet sites, *there is no mechanism related to diagnostic testing reimbursement* where, as here, the insurer fails to meet its statutory obligations to reimburse the provider. Section 3202(b) demonstrates Congress knows how to create an administrative enforcement mechanism, and Congress chose not to as to § 3202(a).

There is certainly no mechanism in the CARES Act to which providers may otherwise avail themselves (absent an implied cause of action) to obtain reimbursement from unwilling insurers under § 3202(a). Further, no administrative agency has declared, either implicitly or explicitly, that it may serve that function. Put simply, although Congress provided a clear directive that insurers reimburse diagnostic testing provider at the publicly-posted cash price, it did not provide any enforcement mechanisms for the

reimbursement right it created in § 3202(a). The complete lack of prescribed enforcement mechanisms further evinces Congress's intent that its rights-creating language in § 3202(a) would be sufficient.

Thus, this factor further demonstrates Congress intended to provide GS Labs with a private right to reimbursement against insurers.

C. A Reimbursement Right Is Consistent with the Purpose of the CARES Act Which Sought to Rapidly Increase Access to COVID-19 Testing.

Third, 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.

The substance of the CARES Act, as well as its legislative history, demonstrate Congress was attempting to address a crisis in a very short period of time. Indeed, the CARES Act was signed into law on March 27, 2020—mere weeks after the COVID-19 lockdowns began. The statute passed the Senate *unanimously*, when multiple members of Congress had tested positive for COVID-19.⁵ President Trump signed it mere hours after the House passed the final version of the bill that first passed in the Senate.

⁵ See Jacob Pramuk, Senate Passes \$2 Trillion Coronavirus Relief Bill—House Aims for Friday Vote, CNBC (Mar. 25, 2020), https://www.cnbc.com/2020/03/25/senate-passes-2-trillion-coronavirus-stimulus-package.html.

Legislators who authored and supported the bill voiced their support for the diagnostic testing provisions of the law, remarking that it would eliminate barriers and increase access to testing. Senator Roy Blunt (R-MO) stated during debate:

we need to do things in this bill that will support healthcare workers and healthcare providers. . . . testing for coronavirus is going to be paid for . . . by private insurance."

166 Cong. Rec. S1076, S1996 (emphasis added).⁶

Senator John Cornyn (R-TX) also expressed the goal of supporting providers:

This bill also makes coronavirus testing free of charge for all Americans, and it includes a range of measures to *support the healthcare professionals who* are literally on the frontlines of this fight.

166 Cong. Rec. S1781, S1792 (emphasis added).⁷

Legislators further recognized the need to greatly expand testing infrastructure to counter the spread of COVID-19 and save lives. Senator Ed Markey (D-MA) stated:

We are at war with the coronavirus, and we need a massive wartime manufacturing mobilization for coronavirus testing kits and personal protective equipment for medical personnel and emergency responders.

. . .

Additionally, hospitals and <u>labs</u> across the Nation are trying to ramp up testing capacity but face shortages in test kits and supplies. *But we need to dramatically scale up testing and ensure our continued ability to test. Our Nation must be able to conduct tens or hundreds of thousands of tests daily, ultimately testing millions of people over the course of our response. That means producing swabs, which we are now running short of, and other testing materials.*

⁶ Available at: https://www.congress.gov/116/crec/2020/03/24/CREC-2020-03-24-senate.pdf.

⁷ *Available at*: https://www.congress.gov/116/crec/2020/03/18/CREC-2020-03-18.pdf.

. . .

This pandemic is unprecedented and will require an unprecedented mobilization and response at every level of society.

166 Cong. Rec. S1781, S1797-S1798 (emphasis added).8

Senator Lamar Alexander (R-TN) opined:

In the end, the only way to end this crisis—and the only way to get the American economy moving again—is to contain the disease. This will require, as soon as possible, adopting a new goal. That goal should be to test every American who needs it for COVID-19 as soon as possible the sooner we make more tests available and stop telling Americans not to get a test, the better.

166 Cong. Rec. S1893, S1895 (emphasis added).9

Senator Richard Durbin (D-IL) similarly stated:

We had a nursing home over the weekend where there was a patent who testified positive for the coronavirus. The Department of Public Health of the State of Illinois went to that nursing home in Willowbrook as a consequence of the first test and tested all of the residents and staff and found 22 tested positive for the coronavirus infection. Naturally, that raised our numbers dramatically. Now we have 160 known cases in our State, in 15 different counties. It is an indication where there is a signal of infection that testing is absolutely essential so we can identify all those who may test positive.

166 Cong. Rec. S1781, S1783 (emphasis added).¹⁰

In another example, Senator Chris Van Hollen (D-MD) reflected:

We are also hearing of shortages in swabs-simple swabs-simply to take the test. We need to ramp up the testing supply. We also need to knock down the barriers to getting tests. We need to adopt the South Korean model, and

⁸ *See supra* note 7.

⁹ Available at: https://www.congress.gov/116/crec/2020/03/22/CREC-2020-03-22-senate.pdf.

¹⁰ See supra note 7.

many of us have been calling for this for a long time. We see States and Governors moving forward with this, but the Federal Government needs to take a much more active role in establishing that infrastructure

166 Cong. Rec. S1879, S1883-S1884 (emphasis added). 11

Representatives in the House made similar statements. For example, Representative Vern Buchanan (R-FL) expressed the following on a precursor bill:

Time is of the essence for my constituents. Why? Because in my District, we already have 3 confirmed cases of Coronavirus. I just finished 2 days of indepth meetings with front-line medical experts at both the Doctors Hospital and Sarasota Memorial Hospital. The message I have today for my colleagues in the House is crystal clear. We need to dramatically ramp-up the supply of test kits, increase the number of locations where people exhibiting symptoms can easily get tested, and accelerate the process of getting results back—hopefully in less than 24 hours.

166 Cong. Rec. H1473, H1494 (emphasis added). 12

As stated, the executive branch, led by then-President Trump, issued guidance explaining that COVID-19 diagnostic testing shall be reimbursable regardless of medical necessity and without regard to insurer prior authorization or other medical management

Available at: https://www.congress.gov/116/crec/2020/03/21/CREC-2020-03-21-senate.pdf.

¹² Available at: https://www.congress.gov/116/crec/2020/03/04/CREC-2020-03-04.pdf.

requirements.¹³ Under President Biden, the executive branch has reaffirmed this guidance and the directive that insurers "shall reimburse" diagnostic testing providers.¹⁴

The executive branch has also provided direction to insurers like Medica as to how they should proceed if they are disinclined to reimburse providers. Notably, the executive branch has *not* advised insurers that they can refuse reimbursement. Rather, the executive branch has reaffirmed that insurers must pay their reimbursement obligations as they come due. The executive branch has also advised insurers they may influence how reimbursement obligations arise in the future through other means: "One way plans and issuers can respond . . . is by giving participants, beneficiaries, and enrollees information about providers who have negotiated rates for COVID-19 testing with the plan or issuer . . . and encourage[e] participants, beneficiaries, and enrollees to rely on these providers." As stated, under the FFCRA and CARES Act, Congress did not give insurers any discretion in determining whether or when they "shall reimburse" providers for COVID-19 diagnostic testing, or discretion in choosing rates at which to reimburse providers. Instead, Congress

¹³ See, e.g., FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43, at 2 & n.6, 7, 9-10 (June 23, 2020), https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf; FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, at 2, 6-7 (Apr. 11, 2020), https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf.

¹⁴ Supra note 4.

¹⁵ Supra note 4 at 1.

¹⁶ *Supra* note 4 at 4-5.

and the President required that insurers reimburse providers for diagnostic testing at publicly-posted cash prices if there is no negotiated rate. Insurers may not refuse to pay.

Implying a private cause of action also carries out the CARES Act's purpose of ensuring revenue to cover the substantial investments necessary for the start-up and operations of new providers of diagnostic testing—such as GS Labs—which were desperately needed in a very short amount of time. (Thompson Decl. $\P\P$ 3, 5.) Without a means for testing providers to obtain reimbursement, these providers would not have been able to finance their substantial investments in establishing additional testing locations and providing quick results. (*Id.* \P 6.) They would face the risk of ceasing operations (*id.* \P 7), leading to less testing availability, in contravention of federal law and policy objectives.

It would also completely defy Congress's objective to increase testing capacity and accessibility if there were <u>no mechanism whatsoever</u> 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 implementation of that legislative purpose when insurers unlawfully withhold reimbursement.

Therefore, the legislative history of the CARES Act evidences Congress's intention to provide a right of action to obtain unlawfully denied reimbursement for diagnostic testing providers that met Congress's call to quickly test every American. To hold that providers who answered Congress's call, in reliance on the plain terms of the CARES Act, in a time of dire national crisis—and who continue to do so—have no recourse would

undermine federal law and undercut the essential coordination of the public and private sectors. The Court must find that this factor favors a private cause of action.

D. Pandemic Response Is Inherently Interstate (and even International), and Is Not a Matter That Has Ever Been Left Solely to the States.

Finally, the pandemic implicates national concerns and requires a national response, making it appropriate to infer a federal private cause of action.

Over the past century, responding to pandemics has been a federal (and international) matter that has not ever been left by Congress solely to the states. Indeed, in every major pandemic over the last 100 years, Congress has enacted legislation at the federal level to respond to the national disaster of the time.

For example, in 1955, Congress enacted, and President Eisenhower signed, The Polio Vaccine Assistance Act, to provide grants to states to purchase vaccines and implement vaccination programs.¹⁷ In 2009, the federal government declared a national emergency under the Public Health Service Act (enacted in 2000), in response to H1N1

¹⁷ See Pub. L. 84-377, 69 Stat. 704 (1955), available at https://www.govinfo.gov/app/details/STATUTE-69/STATUTE-69-Pg704/summary.

influenza (a/k/a "swine flu"). ¹⁸ Congress, in turn, enacted the Supplemental Appropriations Act of 2009 to provide resources to respond to the emerging pandemic. ¹⁹

Polio and swine flu are just a few examples of historic federal responses to national disasters in the form of viral plagues. The CARES Act—a 355+ page bill that was intended to immediately address numerous issues, across multiple subjects, to protect the public health and safety during the COVID-19 pandemic, and which contains the largest economic stimulus package in United States history—is Congress's most recent response to such a crisis. The COVID-19 pandemic has now claimed over 750,000 American lives.

Pandemics historically and practically transcend state-only concerns. Pandemics are similar in kind to securities registered on national and international exchanges, as well as civil rights that apply to all citizens regardless of state.

The plain and unambiguous language mandating reimbursement to providers of diagnostic testing, the lack of any alternative enforcement mechanisms, the legislative history showing Congress and the President intended to increase access and remove financial barriers to testing, and the historical fact that pandemics require a national

¹⁸ See Declaration of a National Emergency with Respect to the 2009 H1N1 Influenza Pandemic, White House (Oct. 24, 2009),

https://obamawhitehouse.archives.gov/realitycheck/the-press-office/declaration-a-national-emergency-with-respect-2009-h1n1-influenza-pandemic-0; 2009 H1N1 Flu Outbreak: Determination that a Public Health Emergency Exists, U.S. Dep't Health & Human Servs. (Apr. 24, 2009), https://www.phe.gov/emergency/news/healthactions/phe/Pages/h1n1.aspx.

¹⁹ Pub. L. 111-32, 123 Stat. 1776 (2009), *available at* https://www.govinfo.gov/app/details/PLAW-111publ32.

response (not merely state action) all demonstrate that, in enacting the CARES Act, Congress intended to create a private cause of action in favor of diagnostic testing providers against insurers for reimbursement of either negotiated rates or publicly-posted cash prices. It would be contrary to Congress's purposes and intent to unjustly enable large insurers like Medica to skirt Congress's directive that it "shall reimburse" providers like GS Labs by holding there is no such implied cause of action. For these reasons, the Court should hold that GS Labs has a private cause of action against Medica in these circumstances.

CONCLUSION

For the reasons stated above, and the reasons that will be stated in its forthcoming reply in support of this motion, GS Labs respectfully requests the Court enter judgment in its favor on these two pure questions of law.

Respectfully submitted,

Dated: November 12, 2021

WINTHROP & WEINSTINE, P.A.

s/ Thomas H. Boyd

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UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

GS LABS, LLC, a Nebraska limited liability company,) Case No.: 21-cv-2400 (SRN/TNL)
Plaintiff,)
v.) LR 7.1(f) CERTIFICATE OF COMPLIANCE
MEDICA INSURANCE COMPANY, a Minnesota insurance corporation,)))
Defendant.)))

I, Thomas H. Boyd, certify that Plaintiff's Memorandum in Support of its Motion for Partial Summary Judgment complies with Local Rule 7.1(f).

I further certify that, in preparation of the above document, I used the following word processing program and version: *Word 2019* and that this word processing program has been applied specifically to include all text, including headings, footnotes, and quotations in the following word count.

I further certify that the above document contains the following number of words: 5,331.

Dated: November 12, 2021

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