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8	IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON			
9		T SEATTLE		
10	PREMERA BLUE CROSS,			
11	Plaintiff,			
12	vs.	Case No. 2:21-cv-1399		
13	GS LABS, LLC,	COMPLAINT JURY		
14	Defendant.	DEMAND		
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16	Premera Blue Cross brings this	Complaint against GS Labs, LLC, and alleges as		
17	follows.			
18	NATURI	E OF THE ACTION		
19	1. This case concerns a laboratory that has attempted to exploit the COVID-19			
20	pandemic—and the extraordinary legislation Congress enacted to combat the pandemic—for it			
21	own financial gain.			
22	2. GS Labs is a Nebraska-based 1	aboratory system that provides COVID-19 testing at		
23	sites in Iowa, Minnesota, Nebraska, Oregon, and Washington. In order to increase the amount			
24	it may bill insurers, it systematically subj	ects patients to expensive and medically unnecessary		
25	testing. In the words of one former employ	yee, it "manipulates people into thinking they need all		
26	three Covid [sic] tests" that GS Labs offe	rs, such that "[p]atients are being lied to just so th[e]		
27	company can make a profit."			
	COMPLAINT – 1	KILPATRICK TOWNSEND & STOCKTON LLP 1420 FIFTH AVENUE, SUITE 3700 SEATTLE WA 98101		

(206) 626-7713 FAX: (206) 260-8946

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3. GS Labs also frequently fails to maintain acceptable quality levels in its testing and reporting of results. In one incident, GS Labs failed to timely report the results of 200 tests, leading one individual who ultimately tested positive to "walk[] around with COVID for a week," potentially spreading the virus.¹ GS Labs has billed Premera for hundreds of COVID-19 tests (if not more) that were, by its own admission, tainted by "deviat[ions] from applicable laboratory standards for testing facilities" that "may have impacted [patients'] test results."

4. Despite these shortcomings, GS Labs charges extraordinarily high prices ranging
from \$380 to \$979 per test. These prices are in some cases *ten times* higher than those charged
by other labs. But GS Labs maintains that insurers must pay these high prices, irrespective of
its illegal testing practices and the quality of its work, due to the Coronavirus Aid, Relief, and
Economic Security Act (CARES Act).

5. Congress passed the CARES Act² at the outset of the COVID-19 pandemic. The Act
requires that, in the absence of an agreement to other rates, health insurers must reimburse
laboratories for COVID-19 testing at the "cash price" they post to their respective websites.³
Federal regulations implementing the CARES Act define "cash price" as "the charge that
applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic
test."⁴

6. GS Labs has posted extremely high prices for COVID-19 testing on its website,
contending that they are its "cash prices" for purposes of the CARES Act. On that basis, it has
attempted to force insurers (including Premera) to pay these exorbitant prices, threatening to
sue them, and to report them to federal authorities, unless they pay in full.

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7. But GS Labs' "cash prices" are a sham. For individuals paying cash, GS Labs charges rates that are less than *one third* of those it has posted to its website. It has attempted to

 ¹ Lauren Melendez, KCTV5, "I walked around with COVID for a week, because of late results." GS Labs, subcontractor issue delays COVID info (Dec. 19, 2020), https://tinyurl.com/45j9nwsv.
 ² Dela L. Na 116 (126 124 State 281 (2020))

 ²⁰ ² Pub. L. No. 116-136, 134 Stat. 281 (2020).
 ³ CARES Act § 3202(a).
 ⁴ 85 EP 71142, 71152 (Nay, 6, 2020).

⁷ ⁴ 85 FR 71142, 71152 (Nov. 6, 2020). COMPLAINT – 2

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obscure that fact by offering every cash-pay patient a "discount" of at least 70% on its "cash 1 prices," without noting that fact in its "cash price" disclosure. GS Labs has thus misrepresented 2 its "cash prices" in an effort to deceive Premera and other insurers into paying rates that far 3 exceed the reasonable value of its services. 4

5 8. Finally, in order to ensure payment, GS Labs peppers its claims with falsehoods. For example, virtually every claim GS Labs has submitted to Premera has indicated that the patient 6 complained of COVID-19 symptoms or exposure. In some instances, the claims reflect unusual 7 and extremely serious diagnoses. But GS Labs does not perform individual patient assessments, 8 9 and includes these false diagnoses in an effort to obtain higher payments. In particular, doing so conceals the fact that at least some of the testing performed by GS Labs is not subject to the 10 CARES Act's "cash price" requirement, such as screen testing for workplace safety. Moreover, in some cases, GS Labs has submitted claims to Premera for tests it did not perform at all. 12

9. Premera paid GS Labs roughly \$10,000 from health plans it fully insures or 13 administers for COVID-19 testing, some or all of which it has learned was not payable for the 14 15 reasons discussed herein. GS Labs has submitted additional claims to Premera for which it seeks further payments totaling more than \$26 million. It has threatened legal action, and to 16 report Premera to state and federal authorities for purported CARES Act violations, if Premera 17 does not pay in full. 18

10. Premera is entitled to recoup the amounts it paid for medically unnecessary, 19 unauthorized, and faulty testing. Premera further disputes that it owes the amount GS Labs 20 claims. GS Labs is neither entitled to payment at the extraordinarily high rates it demands, nor 21 for its medically unnecessary, unauthorized, or faulty testing. 22

11. Premera has attempted to negotiate with GS Labs, but GS Labs will not accept 23 payment at reasonable rates. GS Labs continues to submit claims to Premera with extremely 24 25 high billed charges, and to demand payment in full from Premera.

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COMPLAINT - 3

12. Premera brings this action to recover the losses GS Labs has caused through its unlawful and deceptive actions, to dispel the cloud of legal uncertainty created by GS Labs' demands for excessive payment, and to enjoin GS Labs' continuing inequitable conduct.

PARTIES

13. Premera Blue Cross is a nonprofit corporation incorporated in Washington, with its principal place of business in Mountlake Terrace, Washington. Premera offers fully insured health plans and serves as an administrator for self-funded insurance plans.

8 14. Defendant GS Labs, LLC is a limited liability company formed under the laws of
9 Nebraska. In public filings with various state governments, GS Labs states that its principal
10 place of business is located in Omaha, Nebraska.

11 15. According to public records, GS Labs' members are Daniel White, Christopher
12 Erickson, and Gabriel Sullivan. These individuals are all residents of Nebraska.

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JURISDICTION AND VENUE

14 16. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332
15 because there is complete diversity of citizenship between Premera and GS Labs and the
16 amount in controversy exceeds \$75,000.

17 17. This Court also has subject matter jurisdiction over this action under 28 U.S.C. 18 § 1331 because it arises under the Constitution, laws, or treaties of the United States. 19 Specifically, Premera asserts a claim under the Employee Retirement Income Security Act of 20 1974 (ERISA), 29 U.S.C. § 1001 *et seq.* Premera has standing to bring its ERISA claim as a 21 claims administrator of self-funded health plans. The Court further has subject matter 22 jurisdiction over Premera's state and common law claims under 28 U.S.C. § 1367, as those 23 claims are so related to the federal claim that they form part of the same case or controversy.

18. This Court has personal jurisdiction over GS Labs because this case arises out of
activities GS Labs conducted in, and directed to, Washington State. In particular, it arises out of
COVID-19 testing GS Labs performed on Washington residents at testing sites it maintains in

COMPLAINT - 4

Washington State, and out of insurance claims GS Labs submitted to Premera in Washington
 State related to that testing.

19. Venue is proper in this district under 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claims in this action have occurred in this district. Specifically, GS Labs maintains three of its Washington State testing sites in this district.

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BACKGROUND

Premera's Fully Funded and Self-Funded Health Plans

20. Premera is a health insurance company serving Washington and Alaska.

9 21. As relevant to this litigation, Premera both offers fully funded health plans, and
10 provides administrative services for self-funded health plans.

22. Premera both funds and administers its fully funded plans. Premera pays claims
submitted to its fully funded plans out of its own assets.

23. Premera's self-funded plans, or Administrative Services Only ("ASO") plans, are
funded by contributions from their respective sponsor employers and member employees.
Many of Premera's ASO plans, including plans at issue in this litigation, are subject to ERISA.

24. Premera provides administrative services for ASO plans pursuant to Administrative
Services Agreements, which identify the respective rights and obligations of Premera and the
plan sponsors. Premera serves as a fiduciary of its ASO plans that are subject to ERISA.

25. Premera acts as claims administrator and has been delegated the authority to pursue
recovery of payments made by Premera on behalf of certain self-funded plans covered by
ERISA. Premera has standing to sue under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), for
declaratory and injunctive relief to enjoin any acts or practices that violate the provisions of the
plans and to obtain other appropriate relief to redress violations of and enforce plan terms.

24 26. Premera will provide further details concerning the health plans and claims at issue25 in this litigation following the entry of a HIPAA qualified protective order.

26 27. Beyond health plans Premera insures or administers, Premera serves members of
 27 other Blue Cross Blue Shield companies through the BlueCard program and National Account
 COMPLAINT – 5

Service Company (NASCO). With respect to both, Premera processes and pays claims for
 members of other Blue Cross Blue Shield companies in the first instance.

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The CARES Act and Applicable Regulations and Guidance

28. In response to the COVID-19 pandemic, Congress passed the Families First Coronavirus Response Act ("FFCRA") on March 18, 2020.⁵

29. The FFCRA requires, in relevant part, that health insurers cover approved forms of COVID-19 testing at no cost to patients.⁶

30. It further provides, in a subsection titled "ENFORCEMENT," that "the Secretary of
Health and Human Services, Secretary of Labor, and Secretary of the Treasury" are charged
with enforcing this provision of the Act.⁷

31. On March 27, 2020, Congress supplemented the FFCRA with the CARES Act,
which (among other things) governs reimbursement for COVID-19 testing. The CARES Act
states, in relevant part:

(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:

(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.⁸

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26 ⁵ Pub. L. No. 116-127, 134 Stat. 178 (2020). ⁶ FFCRA § 6001(a). ⁷ *Id.* § 6001(b).

 $\begin{array}{c} 27 \\ 8 \\ CARES \\ Act \\ 8 \\ 3202(a). \\ COMPLAINT - 6 \end{array}$

KILPATRICK TOWNSEND & STOCKTON LLP 1420 FIFTH AVENUE, SUITE 3700 SEATTLE, WA 98101 (206) 626-7713 FAX: (206) 260-8946 32. The CARES Act requires "each provider of a diagnostic test for COVID–19 [to] make public the cash price for such test on a public internet website of such provider," and subjects providers who fail to do so to monetary penalties.⁹

33. Providers must post their "cash price" in a centralized, easy-to-find location, and must include "[a]ny additional information as may be necessary for the public to have certainty of the cash price that applies to each COVID-19 diagnostic test."¹⁰ As explained by the Centers for Medicare & Medicaid Services ("CMS"), "if the provider offers the same test at a different cash price that is dependent on location or some other factor, then on its website listing of cash prices, the provider must indicate all the cash prices that apply to the test and relevant distinguishing information as to when each different cash price applies."¹¹ Similarly, COVID-19 test pricing must be available "[w]ithout having to submit personal identifiable information."¹²

34. Federal regulations issued by CMS implementing the CARES Act define "cash
price" to mean "the charge that applies to an individual who pays cash (or cash equivalent) for
a COVID-19 diagnostic test."¹³

35. CMS explained this definition in its interim final rule as follows:

The "cash price" is generally analogous to the "discounted cash price" as 17 defined at 45 CFR 180.20 for purposes of the Hospital Price Transparency final 18 rule. As we explained in that rule, providers often offer discounts off their gross 19 charges or make other concessions to individuals who pay for their own care 20 (referred to as self-pay individuals). . . . We also stated that the discounted cash 21 price may be generally analogous to the "walk-in" rate that would apply to all 22 self-pay individuals, regardless of insurance status, who pay in cash at the time 23 of the service, and that such charges are often lower than the rate the hospital 24

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⁹ *Id.* § 3202(b).
¹⁰ 85 FR at 71204.
¹¹ *Id.* at 71153.
¹² *Id.* at 71204.
¹³ *Id.* at 71142.
COMPLAINT - 7

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negotiates with third party payers because billing self-pay individuals would not require many of the administrative functions that exist for hospitals to seek payment from third party payers (for example, prior authorization and billing functions). It is therefore our expectation that the "cash price" established by the provider will be generally similar to, or lower than, rates negotiated with innetwork plans and insurers.¹⁴

36. CMS has clarified that certain kinds of testing for COVID-19 are not subject to the "cash price" provisions of the CARES Act. In particular, this provision does not apply to "testing for general workplace health and safety, for public health surveillance, or for other purposes not primarily intended for individualized diagnosis or treatment of COVID-19."¹⁵

11 37. CMS has raised concerns that the "cash price" requirement may lead to "price 12 gouging," and has requested comment on "authorities and safeguards that could be used to 13 mitigate concerns for price gouging both for group health plans and issuers and for consumers 14 receiving a COVID-19 diagnostic test."¹⁶ It has explained that while "most providers have been 15 pricing COVID-19 tests at reasonable levels, generally consistent with reimbursement rates set 16 by the Medicare program, . . . some providers have not done so and are using the public health 17 emergency as an opportunity to impose extraordinarily high charges."¹⁷

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GS Labs and its Unlawful Testing Practices

38. GS Labs is a laboratory system founded in January of 2020. It operates COVID-19
testing sites throughout the United States. Four of those sites are located in Washington State:
one in Federal Way, one in Lynnwood, one in Bellevue, and one in Vancouver. It is out-ofnetwork with Premera—*i.e.*, it has no contract with Premera to serve Premera insureds.

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27 <u>https://tinyurl.com/n74pbah5.</u> COMPLAINT – 8

¹⁴ *Id.* at 71152.

 ¹⁵ CMS, FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44 (Feb. 26, 2021), https://tinyurl.com/n74pbah5.

^{26 &}lt;sup>16</sup> 85 FR at 71153. ¹⁷ HHS, FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44 (Feb. 26, 2021),

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39. There are many other testing sites near each of GS Labs' Washington locations offering the same or similar testing services: four within ten miles of the Federal Way site, five within ten miles of the Lynwood site, three within ten miles of the Bellevue site, and ten within ten miles of the Vancouver site. These other providers offer COVID-19 testing at a fraction of the price charged by GS Labs, and without the endemic quality problems discussed below that have plagued GS Labs.

40. GS Labs' testing sites serve high volumes of patients with short appointments. It has represented that its testing sites can accommodate as many as 1,000 patients a day.

41. Typically, patients remain in their cars throughout the appointment, and nurses obtain samples for testing through the car window. Below is a photo of one representative testing site in Lee's Summit, MO:



42. As relevant here, the tests GS Labs offers are:

a. **Rapid Antigen testing:** These tests require a nasal swab of the patient. They detect protein fragments indicating COVID-19 infection, and produce results quickly—typically in as little as 20 minutes. These tests are relatively cheap and are highly effective in detecting most COVID-19 infections.

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- b. **Polymerase Chain Reaction ("PCR") testing:** These tests require a nasal or oral swab of the patient. GS Labs offers three forms of PCR testing:
 - i. COVID-19 PCR testing: These tests detect genetic material indicating COVID-19 infection. Most labs are able to produce results for COVID-19 PCR tests within 24 hours. While these tests are slower and somewhat more expensive than rapid antigen tests, they are also slightly more effective at detecting COVID-19 exposure early on.
- ii. Bio-Fire PCR testing: These tests are like COVID-19 PCR tests, but detect 21 respiratory pathogens in addition to COVID-19. They are significantly more expensive than COVID-19 PCR tests and provide no additional benefits related to detecting COVID-19 infection.
- iii. GenMark ePlex Respiratory Pathogen 2 Panel testing: These tests are also like COVID-19 PCR tests, but detect 20 respiratory pathogens in addition to COVID-19. They too are significantly more expensive than COVID-19 PCR tests and provide no additional benefits related to detecting COVID-19 infection.
 - c. Rapid Antibody testing: These tests require a blood sample from the patient. Unlike the tests discussed above, rapid antibody testing does not detect current COVID-19 infection. Rather, it detects antibodies that develop after COVID-19 exposure, which can indicate prior COVID-19 infection.¹⁸

43. The appropriate test to administer among those listed above depends on the patient's needs and circumstances. Typically, it is appropriate to administer only one test.

44. FDA guidance explains that, when deciding between antigen and PCR tests for
asymptomatic patients, providers generally should "consider" the most "sensitive" COVID-19

27 Complaint should that change. COMPLAINT – 10

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 ¹⁸ As of the filing of this Complaint, GS Labs has recently begun offering an additional type of test: a small respiratory panel that detects COVID-19, as well as three other respiratory pathogens, which it has priced at \$499 per test. GS Labs has not yet submitted an appreciable number of claims for this test to Premera, but Premera reserves the right to amend its

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test that can be performed without a "prolonged" delay in results.¹⁹ Patients need only undergo
 both antigen and PCR testing when a PCR test is required to confirm an antigen test result. And
 for most patients, "[i]t is not necessary to perform confirmatory high sensitivity molecular tests
 [(*i.e.*, PCR tests)] on individuals with negative antigen test . . . results."²⁰

5 45. Moreover, rapid antibody testing serves a diagnostic purpose only in very limited circumstances. The CDC has explained that antibody testing generally "should not be used to 6 establish the presence or absence" of COVID-19 infection. Similarly, "it is not currently known 7 whether a positive antibody test result indicates immunity against SARS-CoV-2; therefore, at 8 this time, antibody tests should not be used to determine if an individual is immune against 9 reinfection." Instead, antibody testing only serves a diagnostic purpose when (1) administered 10 more than a week after the onset of acute illness that may be COVID-19; or (2) when patients 11 present with late complications of COVID-19 illness.²¹ The CARES Act only applies to 12 antibody testing in these limited circumstances. And Premera's policies only cover antibody 13 testing when utilized for diagnostic purposes as outlined above.²² 14

46. There are virtually no circumstances under which it is medically appropriate to
perform an antibody test in conjunction with an antigen test—and certainly not both an antigen
test *and* a PCR test.

47. Despite the foregoing, GS Labs routinely administers *each* type of test to *each*patient whenever possible—so long as that patient has commercial insurance. GS Labs
administers these medically inappropriate tests solely to increase the amount it may bill to
insurers.

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- ¹⁹ Notably, because GS Labs does not have testing facilities in Washington capable of performing PCR tests, it is incapable of providing PCR test results to Washington residents without delays lasting at least several days.

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 ²⁰ FDA, A Closer Look at Coronavirus Disease 2019 (COVID-19) Diagnostic Testing (Feb. 2021), <u>https://tinyurl.com/fspy33bu</u>.

^{26 &}lt;sup>21</sup> CDC, Interim Guidelines for COVID-19 Antibody Testing (Mar. 17, 2021), <u>https://tinyurl.com/3vx4wwfa</u>.

²⁷ Premera Blue Cross, *BENEFIT COVERAGE GUIDELINE – 2.04.518 SARS-CoV-2 Serology* (Antibody) Testing (Mar. 2, 2021), <u>https://tinyurl.com/2y8sxmhj</u>. COMPLAINT – 11 KILPATRICK TOWNSEND & STOCKTON LLP

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48. GS Labs treats insured and uninsured patients very differently. Notably, it accepts only commercial insurance or cash payment. It does not accept Medicare, which covers much of the elderly population most vulnerable to COVID-19, or Medicaid, which covers financially distressed individuals who may have difficulty paying for COVID-19 testing out-of-pocket.

49. In order to book an appointment, GS Labs requires insured patients to consent to receive a "Rapid Antibody test," "Rapid Antigen test," *and* a "COVID-19 PCR and respiratory panel test." This is so regardless of why the patient seeks COVID-19 testing. Insured patients cannot select a specific test in advance.

50. Because GS Labs buries this information in a "clickwrap" agreement, patients often
are not aware that they have agreed to this unusual term. For example, in a complaint to the
Washington State Attorney General's Office, one consumer stated:

I thought I had Covid and went to GS Labs in Federal Way on Sunday after finding them online for a rapid Covid test. They were the only ones open Sunday. Upon arrival I was never asked if I wanted an antibody test, or a PCR test, yet after my visit was complete I got emails that they were running those tests. I am contesting having to pay for those. It was not made clear to me I would get those or be charged for those.

18 51. In contrast, cash-pay patients *must* select a specific test to book an appointment.
19 This serves as a tacit acknowledgement by GS Labs that performing multiple tests on insured
20 patients is not medically necessary.

52. GS Labs' policies require nurses to at least attempt to administer all three tests to every insured patient. According to interviews with ex-GS Labs personnel, nurses are generally expected to administer all three tests to every patient, and must explain tests that are "missing" (*i.e.*, not performed on a given patient). GS Labs tracks the number of tests performed by each of its nurses, praising those who succeed in administering multiple tests to patients, while punishing those who do not—including by terminating their employment.

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COMPLAINT – 12

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53. As a result, GS Labs' nurses aggressively push multiple tests on patients, and regularly provide false and misleading information about the tests. For example, Premera is aware of instances in which GS Labs' nurses have falsely told patients that rapid antibody testing can detect active COVID-19 infection, can determine whether a patient has developed immunity to COVID-19, and that insurance covers antibody testing in every instance. Nurses also tell patients (falsely) that it is standard medical practice to administer all three types of tests together.

8 54. Premera's interviews are corroborated by public statements by other ex-employees,
9 such as the following:

10[GS Labs] manipulates people into thinking they need all three Covid tests11(antibody, antigen, and PCR). The nurses were told to go to the cars and12immediately start doing the antibody test (finger stick) to distract the patient.13Nurses were being let go if they didn't persuade enough people to get all three14tests. Management would follow the nurses to make sure they were getting15patients to do all three tests (even if they weren't needed). Patients are being lied16to just so this company can make a profit.

17 55. Another former employee lodged the following complaint with a state regulator,18 raising similar concerns:

Starting the week of 1/11/21 we were told we needed to get every person to take 19 20 the antibody test as insurance will pay for both. I inquired about what the "runners"/check-in people were saying after being yelled at by multiple cars for 21 confirming they were having both tests done when they did not want that. . . . 22 On 1/18/21 the lead RN, Paula Berg, shadowed me after telling me my numbers 23 were the lowest. She told me the other new lead RN informs people the antibody 24 25 test confirms the antigen test She observed me sell and educate patients on the extra test and the following day fired me for not selling enough tests. She 26 claims this came from HQ in Omaha. . . . I hope you can work to revoke the 27

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business licenses for their locations upon finding the negligence and fraudulent insurance billing/unethical practices of telling patients the antibody test has actual clinical value for diagnostics (and even if they are contagious- which is erroneous as IgM antibodies can last a month after exposure) or not even tell patients why they are getting the test done.

56. In order not to receive all three tests, patients must affirmatively refuse to undergo the additional, unnecessary testing, contrary to the urging of GS Labs' nurses.

57. Similarly, GS Labs regularly performs and bills insurers for expensive and unnecessary Bio-Fire and GenMark respiratory panel tests, which detect numerous pathogens unrelated to COVID-19, without informing patients. Again, GS Labs does so solely to pad its claims to insurers. There is no medical reason to regularly perform large panel tests on patients who seek only COVID-19 testing. Indeed, the federal government has prosecuted this practice as health care fraud.²³

58. GS Labs' nurses do not individually assess patients before urging them to submit to multiple tests. In fact, GS Labs instructs its nurses not to ask questions of patients. At no point does any medical professional associated with GS Labs evaluate the medical needs of a patient before recommending or performing tests.

59. Instead, GS Labs relies solely on intake paperwork for insured patients that requires patients to check a box stating, "I acknowledge that I am seeking a diagnostic test."

60. This box appears near a disclaimer that reads: "GS Labs only accepts insurance patients who are seeking testing for diagnostic purposes. Patients must be experiencing Covid-19 symptoms or have had a potential exposure to Covid-19 to qualify for a medically necessary diagnostic test." GS Labs requires no similar certification for cash-pay patients.

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²³ See Indictment, United States v. Malena Badon Lepetich, Case No. 3:21-cr-00032 (May 20, 27 2021). COMPLAINT - 14

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61. GS Labs treats this deliberately vague and confusing certification as an affirmation that *every* insured patient has had possible COVID-19 exposure or symptoms. Given the high volumes of insured patients GS Labs serves, GS Labs knows that this is not the case.

62. Indeed, despite this certification, GS Labs still accepts patients who indicate elsewhere in their intake paperwork that they have not had potential COVID-19 exposure or experienced COVID-19 symptoms. Similarly, even when insured patients have specifically informed GS Labs nurses that they had neither potential COVID-19 exposure nor symptoms, GS Labs' nurses not only proceeded with testing, but also continued to urge the patient to undergo multiple tests.

63. Moreover, Premera understands from interviews with ex-employees that GS Labs has performed a significant amount of screen testing for workplace safety. GS Labs personnel were aware that the patients at issue sought testing for that purpose. This sort of screen testing is not diagnostic in nature, not subject to the CARES Act, and not covered by Premera's policies.²⁴

64. GS Labs performs all of its testing nationwide under the auspices of standing orders
issued by Steve W. Powell, M.D., a psychiatrist based in Franklyn, NH. Dr. Powell plays no
role in assessing patients or directing their treatment.

18 65. These standing orders authorize GS Labs to perform each of the various tests it
19 offers only where patients meet certain criteria. Among other things, the standing orders require
20 that, for each test, patients meet minimum criteria related to COVID-19 exposure or symptoms.
21 They authorize large-panel tests like the Bio-Fire and GenMark respiratory panel tests only for
22 relatively rare patients who fall into a "High Risk Group."

66. The standing orders further include specific procedures that GS Labs must follow
for testing. They require GS Labs' nurses to verify that patients meet the criteria for testing, and
obtain verbal agreement (in additional to written consent) for each test administered.

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²⁴ CMS, *FAQs About Families First Coronavirus* . . ., *supra*. COMPLAINT – 15

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67. GS Labs does not inform its nurses of the contents of these standing orders or train
 its nurses to follow them. GS Labs and its nurses do not adhere to the criteria or procedures set
 out in the standing orders, and instead administer as many tests as possible to every insured
 patient.

68. Premera does not reimburse providers for medically unnecessary and inappropriate testing, or COVID-19 testing performed for non-diagnostic purposes, such as that discussed above. Nor does Premera reimburse providers for medically unauthorized testing, such as that discussed above.

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Endemic Quality Problems with GS Labs' Testing

69. GS Labs has repeatedly failed to control the quality of its testing and reporting of
results. Public records disclose instances in which GS Labs has misreported results, failed to
timely report results, and failed to report results altogether.

70. GS Labs' rate of error is significantly greater than other labs that perform the same
tests for a fraction of the price.

71. In one case, GS Labs failed to timely report the results of nearly 200 COVID-19
tests. This led at least one individual who ultimately tested positive to "walk[] around with
COVID for a week," potentially spreading the virus.²⁵

72. In March of 2021, the Nebraska Department of Health and Human Services
informed GS Labs that its facilities failed to meet the standards necessary to perform clinical
testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and ordered
GS Labs to take remedial measures.

73. As particularly relevant here, GS Labs sent correspondence to certain of Premera's
members—but not to Premera—notifying them that GS Labs had identified a lapse in its
"quality control process" for certain of its PCR testing lasting from "3/17/21 [to] 4/9/21." This
caused it to "deviate[] from applicable laboratory standards for testing facilities" during that

 ²⁵ Lauren Melendez, KCTV5, "I walked around with COVID for a week, because of late results." GS Labs, subcontractor issue delays COVID info (Dec. 19, 2020), https://tinyurl.com/45j9nwsv. COMPLAINT – 16

period of several weeks. GS Labs stated that this lapse in quality control "may have impacted
 [patients'] test results."

74. GS Labs did not inform Premera of this lapse, despite having submitted claims for potentially faulty and inaccurate PCR testing to Premera totaling nearly \$400,000.

75. Premera does not reimburse providers for testing that fails to meet applicable standards for quality and reliability.

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GS Labs' False "Cash Prices" for COVID-19 Testing

76. Despite the above problems with its testing procedures and quality, GS Labs charges insurers exorbitant rates for COVID-19 testing ranging from \$380 to \$979.

77. These prices are significantly out of step with those CMS has deemed
"reasonable"—*i.e.*, prices "generally consistent with reimbursement rates set by the Medicare
program."²⁶ As demonstrated by the following chart, the prices GS Labs charges insurers for
COVID-19 testing well exceed the reimbursement rates set by Medicare Administrative
Contractors, and in some cases are nearly *ten times* Medicare rates.

Test	GS Labs' Posted	Medicare Rate
	Rate	
Rapid Antibody	\$380	\$45.23
Rapid Antigen	\$380	\$41.38
COVID-19 PCR	\$385	\$51.41
GenMark / BIO-	\$979	\$416.78
Fire PCR / RPP		

78. These prices are far higher than those charged by other labs, and bear littlerelationship to the cost of performing such tests (which can be as little as \$20 wholesale for

 ²⁶ HHS, *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 44* (Feb. 26, 2021), https://tinyurl.com/n74pbah5.

antigen testing). Accordingly, GS Labs' rates have led to at least one investigation for price gouging by the Kansas Department of Insurance.²⁷

79. Moreover, these prices bear little relationship to the value of GS Labs' testing, particularly in light of the problems with its testing procedures and quality discussed above. Instead, to the extent GS Labs has attempted to justify its prices, it has claimed to have higher marginal costs than other laboratories, which it insists should be borne by insurers and patients.

80. Under normal circumstances, GS Labs would have no expectation that any insurer would pay its extraordinarily high prices. But GS Labs contends that the COVID-19 pandemic, and the CARES Act, give it a right to force insurers to pay whatever it asks.

81. GS Labs has posted the above prices to its website, contending that they are its "cash prices" for purposes of the CARES Act. On that basis, GS Labs demands that insurersincluding Premera-pay these prices in full.

82. But the prices posted to GS Labs' website are not its "cash prices" as that term is defined under the CARES Act. As discussed above, "cash price" under the CARES Act means "the charge that applies to an individual who pays cash (or cash equivalent) for a COVID-19 diagnostic test."28 It is "generally analogous to the 'discounted cash price' . . . for purposes of the Hospital Price Transparency final rule," which accounts for "discounts" providers offer "off their gross charges or . . . other concessions to individuals who pay for their own care."²⁹

83. For individuals paying out-of-pocket, GS Labs charges rates that are less than a third of what it claims to be its "cash prices." It does so by offering every cash-pay patient a 70% "discount" off its purported "cash prices."

84. When booking a testing appointment through GS Labs' website, there are two options: "Bill My Insurance" and "Out-of-Pocket."³⁰ The "Out-of-Pocket" option directs

²⁷ Kyle Palmer, Shawnee Mission Post, Lenexa lab flagged for potential price gouging of COVID-19 tests — what consumers need to know (Dec. 21, 2020), https://tinyurl.com/2ea4vx3y.

²⁶ 85 FR at 71204.

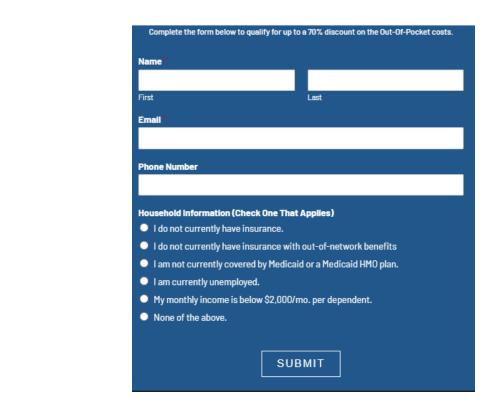
²⁹ *Id.* at 71152. 27 ³⁰ E.g., <u>https://gslabstesting.com/covid-rapid-testing-bloomington/.</u>

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KILPATRICK TOWNSEND & STOCKTON LLP 1420 FIFTH AVENUE, SUITE 3700 SEATTLE, WA 98101 (206) 626-7713 FAX: (206) 260-8946

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patients to "Complete the form below to qualify for up to a 70% discount on the Out-Of-Pocket costs." The following is that form:



85. As reflected above, the form includes radio buttons allowing the user to select "I do
not currently have insurance," "I do not currently have insurance with out-of-network benefits,"
"I am not currently covered by Medicaid or a Medicaid HMO Plan," and "My monthly income
is below \$2,000/mo. per dependent."

86. These options are such that anybody may truthfully select one. Given that insurers must cover COVID-19 testing without cost to patients, most self-pay patients are uninsured and may truthfully select "I do not currently have insurance." But anyone not covered by Medicaid, including individuals who are enrolled in commercial health insurance or Medicare, can truthfully select "I am not currently covered by Medicaid or a Medicaid HMO Plan." And anyone who qualifies for Medicaid, at least in Washington, may truthfully select "My monthly income is below \$2,000/mo. per dependent."

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87. If the user selects any option except "none of the above," and without providing any additional information or verification, he or she receives the following message: 2

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<i>3</i>	Thank you for submitting our Community Financial Assistance							
	Form, Based on your response, you are able to receive a discounted							
5			price on GS Labs Testi	ng services,				
6			On checkout, use the f	ollowing code	to receive 70	% off of th	е	
7			testing service: GSLA	BS70				
8			Select "Book Now" on t	he Out of Poc	ket pricing to	continue.		
9								
10		88. Inj	putting that code while	entering pay	ment inform	ation redu	ces the price	e of testing
11	to l	ess than or	ne third of GS Labs' pos	sted "cash pr	ice," as demo	onstrated b	elow.	
12								
13			Item		Price	Qty	Total	Remove
14		ို ရှိသို့	Covid-19 Standard PCR Test- (Slot - Aug 26,2021 07:03 am (PS		\$ 385.00	1	\$ 385.00	
15			Location: Bellevue Resource: Bellevue 3					
16		Pi	romotion "GSLABS70" applied for "Co	ovid-19 Standard PC	R Test- Out of Pocke	t". Amount Dec	lucted - \$269.50	
17				Additional instruc	tions (300 Chrs)	GSLABS70		🖒 Apply
18					1.	Enter Refe	rral Code	🖒 Apply
19		✓ Credit Card					Subtotal: Discount:	\$385.00 \$269.50
20	E	Billing Inform	ation 🔒				Tax:	\$0.00
21		Cardholder Na	ame				Shipping	\$0.00
22		Card number					Order Total:	\$115.50
23					ර Confirm b	ooking		
24		VISA Matrice	ESSELESS ESSELESS					
25		89 Ar	ny self-pay patient can	easily nay th	e discounted	rate The	foregoing is	consistent
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26			's own investigation, w			-	-	uges casn-
27			ignificantly less than the	e rates posted				FOCKTONIIP
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90. Indeed, in response to a consumer complaint of price gouging, GS Labs has represented to the Washington State Attorney General's Office that "the 'cash prices' listed on GS Labs' website generally are charged only to insurance companies, and *not* consumers," and that GS Labs' purported "'cash prices' apply to insurance companies only." GS Labs further stated unequivocally: "GS Labs has *never* charged a consumer for the 'cash price' of a COVID-19 test, even if they have no health insurance."

91. Notably, even these fractional cash prices are *still* significantly higher than what other labs charge and what CMS has deemed reasonable rates.

9 92. Because GS Labs charges all or virtually all cash-pay patients less than one third of
10 its claimed "cash price," GS Labs has failed to post its "cash price," as that term is defined
11 under the CARES Act. It has instead posted prices that are significantly higher, without
12 disclosing its true "cash prices" on its website in a manner consistent with federal law.

93. In addition to the above, federal regulations implementing the CARES Act make clear that in posting its "cash price," GS Labs must include "[a]ny additional information as may be necessary for the public to have certainty of the cash price that applies to each COVID-16 19 diagnostic test."³¹ As explained by CMS, "if the provider offers the same test at a different cash price that is dependent on location or some other factor, then on its website listing of cash prices, the provider must indicate all the cash prices that apply to the test and relevant distinguishing information as to when each different cash price applies."³²

94. GS Labs' "COVID-19 Pricing Transparency" page omits any reference to the fact
the posted test prices are more than three times higher than the rates charged to cash-pay
patients.³³ This independently violates GS Labs' obligations under the CARES Act.

95. Finally, COVID-19 test pricing must be available "[w]ithout having to submit

personal identifiable information,"³⁴ yet GS Labs requires patients to fill out a form with their

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 $\frac{31}{85}$ FR at 71204.

 $26 \begin{bmatrix} 32 \\ 32 \end{bmatrix} Id. at 71153.$

⁷ ³⁴ 85 FR at 71204. COMPLAINT – 21

^{27 &}lt;sup>33</sup> See https://gslabstesting.com/covid-19-pricing-transparency/.

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personal information before confirming (invariably) that the patient qualifies for a 70% discount. This too violates the CARES Act.

96. Because GS Labs stands in violation of the CARES Act's requirement that it "make public [its] cash price," and has not posted its cash price on its website consistent with federal law, it has no established "cash price . . . listed . . . on a public internet website" for purposes of the CARES Act.

97. Indeed, GS Labs has attempted to deceive Premera and other insurers by obscuring its true cash price and demanding payment at rates three times as great. It has used the CARES Act as a cudgel to threaten and intimidate insurers, knowing all along that it has failed to comply with the Act's letter and spirit.

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GS Labs' Submission of Claims to Premera and Demands for Payment

98. Since February of 2021, GS Labs has submitted more than 80,000 claims to
Premera for COVID-19 testing, with outstanding billed charges well in excess of \$26 million.

99. Premera instituted a pre-payment review process requiring GS Labs to submit
records related to its claims. GS Labs has largely refused to provide these records, resulting in
the denial of most of its claims.

17 100. Many of these claims on their face include tests that appear to be unnecessary,
18 faulty, and not covered by Premera's policies. Among other things:

19a. Many (indeed, most) of the claims reflect multiple tests in medically20inappropriate combinations as a result of GS Labs' policy of pressuring21patients to submit to unnecessary testing. In particular, more than 11,00022claims include all three types of testing GS Labs offers. Similarly, more than2326,000 claims reflect both antigen and antibody testing.

b. Numerous other claims reflect antibody testing standing alone. Given GS
 Labs' testing practices and the very narrow circumstances under which
 antibody testing serves a medically recognized diagnostic purpose, it is

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	virtually impossible that all (or even a substantial portion) of these tests are
	covered under Premera's policies.
c.	Many thousands of the claims pertain to expensive large-panel tests, which
	(to a virtual certainty) were not medically justified. GS Labs submitted more
	than 3,800 claims for large-panel testing standing alone, as well as many
	others in combination with other tests, as discussed above.
d.	403 claims for PCR testing were, by GS Labs' own admission, tainted by a
	"deviat[ion] from applicable laboratory standards for testing facilities" that
	"may have impacted [patients'] test results." GS Labs demands \$394,537 for
	these faulty tests.
101. In a	addition to the above, the claims include information that appears virtually
certain to be fals	e or incorrect.
a.	Nearly all of the claims (over 99%) include Current Procedural Terminology
	(CPT) codes indicating that the patient had exposure to COVID-19. Given
	the volume of testing, as well as the findings of Premera's own investigation,
	it is almost certainly not true that over 99% of the patients at issue had
	COVID-19 exposure.
b	Many claims include other extraordinarily unlikely diagnosis codes used to
	support expensive testing. For example, roughly 1,000 claims list a CPT
	code indicating a diagnosis of acute respiratory distress syndrome-a serious
	(and often deadly) condition in which fluid builds up in the alveoli of the
	lungs, restricting oxygen flow to the bloodstream. It generally develops only
	in individuals who are already critically ill or seriously injured. GS Labs'
	facilities lack the equipment necessary to diagnose this condition.
c.	All or virtually all of the claims include errors with respect to the listed
	National Provider Identifier (NPI), CLIA number, and/or Place of Service
COMPLAINT – 2	23 KILPATRICK TOWNSEND & STOCKTON LLP 1420 FIFTH AVENUE, SUITE 3700 SEATTLE WA 98101

CPT code, obscuring the location and licensure of the laboratory that actually performed the testing.

102. As discussed above, GS Labs largely refused to comply with the pre-payment review process, but did ultimately agree to provide a small sample of medical records for some claims. To the limited extent GS Labs has provided medical records as part of the pre-payment review process, these have confirmed Premera's suspicions and raised additional concerns. The following are just some representative examples, which Premera has anonymized to protect patient privacy:

- a. Patients 1 and 2 both received a rapid antigen test, a rapid antibody test, and a large-panel PCR test on March 15 and 17, 2021, respectively. In both cases, GS Labs billed Premera \$1,789 for the three tests. The claims GS Labs submitted to Premera represented that the patients had exposure to COVID-19. But medical records reflect that the patients indicated they had neither exposure to nor symptoms of COVID-19. These claims were not payable because (1) the tests were medically inappropriate and unjustified; (2) the standing order upon which GS Labs relied did not authorize the tests; and (3) the claim GS Labs submitted included a material falsehood.
- b. Patient 3 received a rapid antigen test, a rapid antibody test, and a small-panel PCR test on March 20, 2021. GS Labs billed Premera \$1,195 for the three tests. The claim GS Labs submitted to Premera represented that the patient had exposure to COVID-19. But medical records reflect that the patient indicated they had neither exposure to nor symptoms of COVID-19. This claim was not payable because (1) the tests were medically inappropriate and unjustified; (2) the standing order upon which GS Labs relied did not authorize the tests; and (3) the claim GS Labs submitted included a material falsehood.
- COMPLAINT 24

- c. GS Labs submitted claims to Premera stating that Patients 4 and 5 received both a rapid antigen test and a confirmatory PCR test on January 13 and 14, 2021, respectively. GS labs billed Premera \$815 per patient. But medical records reflect that Patients 4 and 5 did *not* receive PCR tests. Instead, they received *rapid antibody* tests. The tests GS Labs actually performed were both cheaper than the tests for which it billed Premera, and (as confirmed by medical records) medically unnecessary and not covered by Premera's policies. These claims were not payable because (1) the tests were medically inappropriate and unjustified; (2) the claim GS Labs submitted included a material falsehood; and (3) GS Labs did not actually perform the tests for which it billed.
- d. Patients 6 received a rapid antigen test, a rapid antibody test, and a large-panel PCR test on March 26, 2021. GS Labs submitted claims to Premera totaling \$1,789 for all three tests. It represented that the patient not only had suspected exposure to COVID, but acute respiratory distress syndrome. Medical records failed to support the latter diagnosis, or to show that an antibody test served a valid diagnostic purpose. Moreover, the patient's PCR test results were tainted and rendered unreliable by a lapse in GS Labs' quality assurance procedures for its laboratory, but GS Labs never notified Premera of that fact or withdrew the claim at issue. This claim was not payable because (1) the tests were medically inappropriate and unjustified; (2) the claim GS Labs submitted included a material falsehood; and (3) the test results were tainted and made unreliable by a lapse in quality assurance standards.
 - e. Patients 7 received a rapid antigen test, a rapid antibody test, *and* a largepanel PCR test on March 26, 2021. GS Labs submitted a claim to Premera for \$1,789 for all three tests. It represented that the patient not only had

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suspected exposure to COVID, but acute respiratory distress syndrome. Medical records failed to support either diagnosis (although the patient did indicate that they had some symptoms). The medical records further failed to substantiate that the antibody test served a valid diagnostic function. This claim was not payable because (1) the tests were medically inappropriate and unjustified; and (2) the claim GS Labs submitted included a material falsehood.

f. GS Labs submitted a claim for Patient 8 representing that, on January 22, 2021, Patient 8 received *two* rapid antigen tests, a rapid antibody test, and a large panel PCR test. For these tests, GS Labs billed Premera \$2,219. Medical records Premera received from GS Labs indicate that, in reality, Patient 8 received only a rapid antigen test and a rapid antibody test. This claim was not payable because (1) the tests were medically inappropriate and unjustified; (2) the claim GS Labs submitted included a material falsehood; and (3) GS Labs did not actually perform the tests billed.

16 103. The medical records Premera received also demonstrated further deficiencies with 17 respect to each of the foregoing claims. Each of the above included at least one (and usually 18 more) of the following additional defects: (1) incorrect CLIA number; (2) incorrect NPI; 19 (3) incorrect place-of-service; and (4) incorrect date-of-service. Based on Premera's review, out 20 of the many thousands of claims GS Labs submitted to Premera, there are virtually no "clean" 21 claims—*i.e.*, claims free of material error.

104. The foregoing are just a few representative examples from Premera's review of
medical records. Few (if any) of the claims GS Labs submitted appear to be totally accurate as
compared to the medical records GS Labs produced. The foregoing examples are also
consistent with Premera's investigation regarding GS Labs' testing policies.

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105. Based on Premera's findings with respect to the foregoing claims, as well as its findings discussed in paragraphs 100-02, *supra*, most (if not all) of the more than 80,000 claims GS Labs submitted to Premera are not payable in whole or in part.

106. Based on the foregoing, and on information and belief, most (if not all) of the claims GS Labs has submitted to Premera pertain to testing that was (1) medically unnecessary or inappropriate; (2) unauthorized by a physician's order; and/or (3) faulty and unreliable. Such claims are not payable under Premera's policies. Moreover, in a significant number of cases, GS Labs did not actually perform the testing for which it billed Premera at all. GS Labs presently has exclusive possession of the records that would enable Premera to determine conclusively the full universe of such claims.

107. Similarly, based on the foregoing, and on information and belief, most (if not all)
 of GS Labs' claims are not payable because they include material falsehoods and inaccuracies.
 3 Again, GS Labs presently has exclusive possession of the records that would enable Premera to
 determine conclusively the full universe of such claims.

15 108. Notably, Gabriel Sullivan, one of GS Labs' members, faces a lawsuit brought by a former employer alleging similar misconduct. The complaint in that case states that Sullivan 16 was "responsible for patient services and billing," and "failed to implement policies and 17 procedures that . . . w[ere] in compliance with the contractual requirements and billing policies 18 of insurance companies." Instead, Sullivan "intentionally implemented [billing] procedures that 19 he knew were not compliant with insurance company requirements," leading an insurer to 20 assess an overpayment "in excess of \$1.9 million." It further cites an email that Sullivan 21 allegedly sent stating his intent to "beat [insurers] at their own game and out smart [sic] them" 22 with billing practices that "do[n't] follow their personal guidelines."³⁵ 23

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109. GS Labs regularly submits false and deceptive claims to other insurers as well, including other insurers in Washington.

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³⁵ Complaint ¶¶ 38-40, *LMMC*, *LLC*, *et al. v. Sullivan*, *et al.*, Case No. 8:19-cv-00560 (D. Neb. Dec. 23, 2019). COMPLAINT – 27

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110. GS Labs submitted all of the claims at issue demanding payment at its false and exorbitant "cash prices," discussed above. To the extent the claims are payable at all, they are not payable at these inflated rates. These rates are not required by the CARES Act nor by any other source of law. Premera did not agree to pay these rates (whether explicitly or impliedly), and these rates far exceed the fair market value of GS Labs' work.

111. Premera paid roughly \$10,000 on some of the claims GS Labs submitted from plans it fully insures or administers on behalf of ASO plans. Premera did not owe and should not have paid some (or all) of that amount due to the foregoing misconduct.

9 112. GS Labs contends that it is entitled to payment of well over \$26 million on the 10 remaining claims that it has submitted to Premera. But as discussed above, many of these 11 claims are not payable at all, and to the extent they are, GS Labs is not entitled to payment at 12 the exorbitant rates it demands.

113. GS Labs has threatened Premera with litigation, and to report Premera to federal authorities for CARES Act violations, if Premera will not meet its terms. And GS Labs continues to submit inaccurate claims to Premera for medically inappropriate and unauthorized testing.

CLAIMS FOR RELIEF

COUNT I: VIOLATIONS OF THE WASHINGTON CONSUMER PROTECTION ACT, RCW 19.86, *et seq*.

114. Premera hereby incorporates the foregoing paragraphs as if fully set forth herein and further alleges as follows.

115. The Washington Consumer Protection Act ("CPA") prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." RCW 19.86.020.

116. GS Labs engaged in a variety of "unfair" practices within the meaning of the CPA in conducting its business in Washington. These include:

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1	a. Routinely performing medically unnecessary and unwarranted testing on
2	patients in order to obtain higher payments from insurers;
3	b. Routinely pressuring patients to undergo unnecessary and unwarranted testing,
4	without regard to individual need, to obtain higher payments from insurers;
5	c. Routinely failing to obtain informed consent from patients prior to performing
6	tests in order to obtain higher payments from insurers;
7	d. Routinely performing testing on patients without a physician's authorization in
8	order to obtain higher payments from insurers; and
9	e. Price gouging and exploiting the extraordinary circumstances of the COVID-19
10	pandemic to charge far more than the fair market value of the testing performed.
11	117. The foregoing practices offend established public policy and harm the public
12	interest.
13	118. For example, medical ethics and legal principles require providers of medical
14	services to follow established standards of care and to obtain informed consent from patients
15	prior to performing a medical procedure. ³⁶ Informed consent requires not only that the patient
16	receive complete and accurate information, but that the provider not render the circumstances
17	of consent unduly coercive. ³⁷ The testing practices described above offend the bedrock
18	principles that govern the provision of medical care in Washington.
19	119. Moreover, the Washington Attorney General's office has explained that "[p]rice
20	gouging during an emergency," including the COVID-19 pandemic, "violates the Consumer
21	Protection Act's prohibition on unfair business practices." ³⁸ There is currently a bill pending in
22	the Washington Senate that (once passed) will expressly prohibit charging an "excessive price"
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24	³⁶ See Lisa V. Brock & Anna Mastroianni, University of Washington Dept. of Bioethics &
25	Humanities, <i>Clinical Ethics and Law</i> (last visited Aug. 27, 2021), <u>https://tinyurl.com/2c4tt885</u> . ³⁷ Jessica De Bord, University of Washington Dept. of Bioethics & Humanities, <i>Informed</i>

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 ³⁷ Jessica De Bord, University of Washington Dept. of Bioethics & Humanities, *Informed Consent* (last visited Aug. 27, 2021), <u>https://tinyurl.com/b86jd6rt</u>.
 ³⁸ Washington Attorney General's Office, *AG Ferguson launches "See It, Snap It, Send It" campaign encouraging Washingtonians to report price gouging* (Apr. 7, 2020), <u>https://tinyurl.com/2wc5c76t</u>. 27

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for "health care services."³⁹ Many, if not most, states already have legislation in place forbidding price gouging in this context, and GS Labs is under investigation in at least one such state due to its excessive prices. The foregoing reflects the strong public policy in Washington against price gouging for COVID-19 testing during the pandemic.

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120. As described above, GS Labs also engaged in a variety of "deceptive" practices within the meaning of the CPA in conducting its business in Washington. These include:

- a. Misleading patients as to the medical necessity and propriety of performing multiple COVID-19 tests, thus inducing them to undergo unnecessary and expensive testing, in order to obtain higher payments from insurers;
- b. Misleading patients as to the capabilities of rapid antibody testing, thus inducing
 them to undergo unnecessary and expensive testing, and creating the risk that
 some patients may falsely believe themselves to be immune to COVID-19, in
 order to obtain higher payments from insurers;
- c. Misleading patients as to the circumstances under which rapid antibody testing
 is covered by insurance, in order to obtain higher payments from insurers;
- d. Posting false and deceptive "cash prices" in an effort to mislead the public,
 including insurers like Premera, as to the "cash prices" it charges for COVID-19
 testing, in order to obtain higher payments from insurers; and
 - e. Systematically submitting false and misleading claims to health insurers in the state of Washington that misrepresent patient diagnoses, the medical necessity of the testing performed, and in some cases, the tests actually performed, among other inaccuracies.

121. The foregoing practices were, and remain, likely to mislead reasonable consumers,
and did in fact deceive the public. These practices had the capacity to mislead, and did in fact
deceive, not only patients seeking COVID-19 testing, but also insurers throughout Washington
and in other states.

 ³⁹ Washington Senate Bill 5191, available at <u>https://tinyurl.com/ssacju8</u>.
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122. GS Labs engaged in the foregoing practices in the course of trade or commerce in Washington, and in particular, in the provision of COVID-19 testing services.

123. GS Labs' misconduct affects the public interest. GS Labs subjected many Washington residents to expensive, medically inappropriate, unnecessary, and unauthorized testing without informed consent. GS Labs further misled many members of the public as to the purpose and capability of the tests administered—in particular, the diagnostic value of rapid antibody testing. As discussed above, this is inconsistent with the ethical and legal principles that govern the provision of medical care in Washington.

124. GS Labs' submission of false and misleading insurance claims further affects the 9 public interest. The Washington state legislature has "f[ound] and declare[d] that the welfare of the citizens of this state is threatened by the spiraling increases in the cost of health care," and "that fraudulent health care claims contribute to these increases in health costs [such that] . . . special attention must be directed at eliminating the unjustifiable costs of fraudulent health care claims." It is thus illegal to submit a claim that (1) "falsely represents that the goods or services were medically necessary in accordance with professionally accepted standards"; (2) "knowingly make[s] a false statement or false representation of a material fact"; or (3) "conceal[s] or fail[s] to disclose any information with intent to obtain a health care payment to which the person or any other person is not entitled, or to obtain a health care payment in an amount greater than that which the person or any other person is entitled."40

125. Finally, GS Labs' maintenance of false "cash prices" on its website affects the public interest. CMS has explained that the requirement that providers maintain accurate cash prices on their website is necessary to ensure transparency for "the public, including group health plans and health insurance issuers offering group or individual health insurance coverage 23 that must provide reimbursement for COVID-19 diagnostic testing pursuant to the requirements 24 of section 3202(a) of the CARES Act."41 25

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 ⁴⁰ See RCW 48.80.010, et seq.
 ⁴¹ 85 FR at 71153. 27 COMPLAINT - 31

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126. The conduct described above has a real and substantial potential for repetition-GS Labs has consistently engaged in the conduct described above throughout the period it has operated in Washington, and continues to engage in the above conduct today.

127. GS Labs engaged in the above misconduct in the regular course of its business. GS Labs further advertises to the public, and has actively solicited both patronage by patients and payments by insurers like Premera. GS Labs has unequal bargaining power by virtue of the exigent circumstances created by the COVID-19 pandemic.

128. GS Labs' unfair or deceptive acts and practices injured Premera. Premera has paid roughly \$10,000 on claims GS Labs submitted from plans it fully insures or administers on behalf of ASO plans. Premera did not owe and should not have paid some (or all) of that amount due to the foregoing misconduct. Moreover, GS Labs' has forced Premera to expend significant resources on investigating and addressing the misconduct detailed above, as well as in addressing GS Labs' demands for exorbitant payments.

129. GS Labs' unfair and deceptive acts and practices directly and proximately caused 14 15 Premera's injuries. GS Labs caused these injuries by, among other things, (1) causing patients to undergo medically unnecessary, inappropriate, and unauthorized testing; (2) submitting false 16 and misleading insurance claims to Premera related to that testing; and (3) demanding payment 17 from Premera at false and exorbitant "cash prices," while concealing its true "cash prices." 18

130. By virtue of the foregoing, Premera is entitled to its damages, an injunction prohibiting GS Labs from continuing to engage in the unlawful and inequitable practices described above and enjoining it from seeking payment from Premera's members, and its attorneys' fees and costs.⁴²

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COUNT II: ERISA § 502(a)(3) & 28 U.S.C. §§ 2201 & 2202

131. Premera acts as claims administrator and has been delegated the authority to 24 25 pursue recovery of payments made by Premera on behalf of certain self-funded plans covered by ERISA. Premera has standing to sue under ERISA § 502(a)(3), 29 U.S.C. § 1132(a)(3), for 26

27 ⁴² RCW 19.86.090. COMPLAINT - 32

declaratory and injunctive relief to enjoin any acts or practices that violate the provisions of the plans and to obtain other appropriate relief to redress violations of and enforce plan terms.

132. The ASO plans at issue in this litigation covered by ERISA include the following or substantially similar language: "If Premera makes a payment in error on your behalf to you or a provider, and you are not eligible for all or a part of that payment, Premera has the right to recover payment, including deducting the amount paid mistake from future benefits."

133. Premera will provide additional information regarding the specific plans and claims at issue in this litigation following the entry of a HIPAA qualified protective order.

134. GS Labs has systematically submitted false and misleading insurance claims to Premera's ERISA plans seeking reimbursement for medically unnecessary, inappropriate, and unauthorized testing, at exorbitant prices, as detailed above.

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135. GS Labs' practices are deceptive, unfair, and unlawful.

136. Any claims that Premera has denied, are pending, or that GS Labs may submit in the future that were or are tainted by the conduct described above are not payable and void.

137. There is a *bona fide*, present need for a declaration as to the unlawfulness of GS Labs' conduct. Premera is entitled to a judgment declaring that GS Labs' practices, as described above, violate the terms of Premera's ERISA plans and are not payable and void.

138. Premera further seeks an order enjoining GS from continuing to submit false and misleading insurance claims to Premera's ERISA plans seeking reimbursement for medically unnecessary, inappropriate, and unauthorized testing, at exorbitant prices, as detailed above.

139. Finally, Premera seeks recovery of its reasonable attorney fees and costs, under ERISA § 502(g)(1), 29 U.S.C. § 1132(g)(1).

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COUNT III: DECLARATORY JUDGMENT UNDER 28 U.S.C. § 2201

140. Premera incorporates by reference the above paragraphs as if fully set forth herein 24 and further alleges as follows. 25

141. There is an actual, substantial, and present controversy between GS Labs and 26 Premera concerning the amount of payment (if any) due in connection with claims submitted 27 KILPATRICK TOWNSEND & STOCKTON LLP COMPLAINT - 33 1420 FIFTH AVENUE, SUITE 3700

SEATTLE, WA 98101 (206) 626-7713 FAX: (206) 260-8946 by GS Labs to Premera for COVID-19 testing that Premera has denied or that are currently pending, as well as with respect to the claims that GS Labs continues to submit.

142. First, there is a controversy as to Premera's obligation to pay for COVID-19 testing that it contends was medically unnecessary, inappropriate, and unauthorized for the reasons detailed herein.

143. Second, there is a controversy as to Premera's obligation to pay claims submitted by GS Labs to the extent those claims include material falsehoods (including with respect to whether GS Labs actually performed the tests billed), as detailed above.

144. Third, there is a controversy as to Premera's obligation to pay for COVID-19 testing that GS Labs admits was tainted by "deviat[ions] from applicable laboratory standards for testing facilities" that "may have impacted [patients'] test results."

145. Fourth, to the extent that the claims GS Labs has submitted are payable at all, there is a controversy as to whether Premera is obligated to pay the rates GS Labs demands—*i.e.*, GS Labs' exorbitant claimed "cash prices" under the CARES Act.

146. Premera and GS Labs have adverse legal interests. GS Labs contends that it is entitled to payment in full from Premera totaling more than \$26 million dollars for claims it has submitted, and that it may pursue this amount from Premera through litigation. Although GS Labs has not specifically informed Premera of the legal basis for its potential claims, GS Labs has recently filed suit against another insurer under materially identical circumstances, bringing a purported claim under the CARES Act, a variety of equitable and quasi-contractual claims, and a claim under the relevant state prompt-pay statute.⁴³ On information and belief, GS Labs intends to assert these same or similar claims against Premera. Were GS Labs to bring these claims against Premera, the parties' complete diversity and the amount in controversy would satisfy the prerequisites for subject matter jurisdiction in this Court.

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⁴³ See Answer & Counterclaims, Blue Cross and Blue Shield of Kansas City v. GS Labs, LLC, Case No. 21-cv-00525 (W.D. Mo. Aug. 5, 2021).

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147. Premera contends that it is obligated to pay only a fraction of the claims GS Labs has submitted, if any, due to the misconduct detailed above. Premera further contends that, to the extent it is obligated to pay at all, it need only pay the fair market value of GS Labs' COVID-19 testing, as opposed to the exorbitant rates GS Labs demands.

148. GS Labs continues to submit claims to Premera that raise these same disputes.

149. The controversies between GS Labs and Premera are substantial and of sufficient immediacy and reality to warrant declaratory relief. GS Labs has threatened legal action against Premera if Premera will not pay an amount to its satisfaction. Premera and GS Labs attempted to negotiate a resolution of these controversies, but reached an impasse. At this point, it is clear that the parties cannot reach an amicable resolution of their dispute. Moreover, as discussed above, GS Labs has recently asserted claims against another insurer with which it could not reach an agreement under materially identical circumstances.

13 150. Accordingly, there is a bona fide, actual, present, and practical need for a 14 declaration based upon the foregoing with respect to the claims GS Labs has submitted to 15 Premera, as well as the claims that GS Labs continues to submit to Premera. GS Labs' demands 16 for payment have created a cloud of legal uncertainty as to Premera's liability with respect to 17 an ever-growing number of claims for COVID-19 testing, and Premera faces a present threat of 18 litigation. Premera thus requests a judgment be entered declaring the following:

- a. Neither Premera, nor its members, need pay claims submitted by GS Labs pertaining to medically unnecessary, inappropriate, and unauthorized testing, as described above;
 - b. Neither Premera, nor its members, need pay claims submitted by GS Labs that include material falsehoods, as detailed above;
- c. Neither Premera, nor its members, need pay claims submitted by GS Labs that have been tainted by "deviat[ions] from applicable laboratory standards for testing facilities" that "may have impacted [patients'] test results," or other unacceptable lapses in quality and reliability; and

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1	d. To the extent the claims GS Labs submits are payable at all, Premera is not		
2	obligated under any source of law to pay the rates GS Labs claims to be its		
3	"cash prices," but need only pay rates that are fair and reasonable in light of		
4	the market and the amounts Premera pays other labs for COVID-19 testing.		
5	PRAYER FOR RELIEF		
6	WHEREFORE, Premera respectfully requests an award in its favor and granting the		
7	following relief:		
8	a. Damages as requested herein;		
9	b. Declaratory relief as requested herein;		
10	c. Injunctive relief as requested herein;		
11	d. An award of attorneys' fees;		
12	e. Prejudgment and post-judgment interest; and		
13	f. An award of any other relief in law or equity that the Court deems just and		
14	proper.		
15	DATED this 14 th day of October, 2021.		
16	KILPATRICK TOWNSEND & STOCKTON LLP		
17	By <u>/s/ Gwendolyn C. Payton</u> Gwendolyn C. Payton, WSBA No. 26752		
18	gpayton@kilpatricktownsend.com 1420 Fifth Ave., Suite 3700		
19	Seattle, WA 98101 Telephone: (206) 626-7714		
20	Facsimile: (206) 623-6793		
21	ROBINS KAPLAN LLP		
22	By <u>/s/ Jeffrey S. Gleason</u> Jeffrey S. Gleason (pro hac vice		
23	forthcoming) JGleason@robinskaplan.com		
24	Charlie C. Gokey (pro hac vice forthcoming)		
25	CGokey@robinskaplan.com Stephanie A. Chen (pro hac vice		
26	forthcoming) SChen@RobinsKaplan.com		
27	2800 LaSalle Plaza		
	COMPLAINT – 36 KILPATRICK TOWNSEND & STOCKTON LLP 1420 FIFTH AVENUE, SUITE 3700 SEATTLE, WA 98101 (206) 626-7713 FAX: (206) 260-8946		

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1	800 LaSalle Avenue Minneapolis, MN 55402–2015
2	Minneapolis, MN 55402–2015 T: (612) 349–8500 F: (612) 339–4181
3	Counsel for Plaintiff Premera Blue Cross
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27	COMPLAINT – 37 KILPATRICK TOWNSEND & STOCKTON LLI 1420 FIFTH AVENUE, SUITE 3700 SEATTLE, WA 98101 (206) 626-7713 FAX: (206) 260-8946