UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

NUWAY, Alliance, NUWAY House, Inc., 3 Rs NUWAY Counseling Center. **NUWAY** Saint Cloud Counseling Center, **NUWAY** University Counseling Center, NUWAY Rochester Counseling Center, 2118 NUWAY Counseling Center, NUWAY Mankato Counseling Center, NUWAY Duluth Counseling Center,

Civil File No. 25-CV-00492 (JRT/ECW)

Plaintiffs,

VS.

Minnesota Department of Human Services Temporary Commissioner Shireen Gandhi, in her official capacity,

DEFENDANT'S RESPONSE TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY **INJUNCTION**

Defendant.

INTRODUCTION

Plaintiff NUWAY Alliance and related entities (collectively "Nuway") asks the Court to enjoin DHS from complying with its obligation under state and federal law to temporarily suspend Medicaid payments to a provider where there is a credible allegation of fraud. Nuway makes this extraordinary request while simultaneously conceding that it is under active investigation by the United States Department of Justice for Medicaid fraud with respect to those very services for which DHS seeks to withhold further reimbursement. Nuway attempts to justify its requested relief by seeking to litigate the

substance of the underlying fraud allegations that it suspects are the subject of that investigation, when this is not the forum to do so. Nuway has failed to demonstrate any viable legal theory under which it is likely to succeed on the merits of its action, primarily because it has no legally protectable interest in the continued receipt of Medicaid funds. Nor has Nuway met its heavy burden of proving it is entitled to relief under the other preliminary injunction factors.

In short, Nuway has failed to prove that it is entitled to the extraordinary remedy of enjoining DHS from suspending Medicaid payments—a remedy that would amount to ordering the State of Minnesota to continue paying public funds to a provider that both the United States Department of Justice and DHS have determined is the subject of credible allegations of fraud for which an investigation is pending. The Court should deny Nuway's motion.

STATUTORY AND FACTUAL BACKGROUND

I. THE MEDICAID PROGRAM.

Medicaid is a jointly financed federal-state program established under Title XIX of the Social Security Act. 42 U.S.C. §§ 1396–1396v. Medicaid pays for necessary medical care to certain individuals who do not have enough income or other resources to pay for the medical care they need. *See* 42 U.S.C. § 1396-1; 42 C.F.R. § 430.0; *Ark. Dep't of Health & Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006). In Minnesota, the Medicaid program is administered by the Department of Human Services ("DHS") and is referred to as Medical Assistance or "MA." Minn. Stat. ch. 256B.

Medicaid is Spending Clause legislation "much in the nature of a contract." Armstrong v. Exceptional Child Center, Inc., 575 U.S. 320, 332 (2015) (citing Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981)). The federal government shares the cost of providing medical assistance with states, like Minnesota, that elect to participate in the Medicaid program. See 42 U.S.C. §§ 1396a, 1396b; 42 C.F.R. § 430.0. In return, states must comply with the requirements of the federal statutes and rules of the U.S. Department of Health and Human Services' Center for Medicare and Medicaid Services ("CMS"), which is responsible for implementing the Medicaid program. See 42 U.S.C. § 1396a; Shagalow v. State Dep't of Human Servs., 725 N.W.2d 380, 385 (Minn. Ct. App. 2006); see also Alexander v. Choate, 469 U.S. 287, 289 n.1 (1985).

II. DHS'S SURVEILLANCE AND INTEGRITY REVIEW SECTION.

Because DHS receives and administers federal Medicaid funds, federal regulations mandate that it establish and maintain a "statewide surveillance and utilization control program" that, among other things, "[s]afeguards against unnecessary or inappropriate use of Medicaid services and against excess payments." 42 C.F.R. § 456.3. To discover and correct inappropriate use of Medicaid payments and excess payments, states must conduct post-payment reviews. 42 C.F.R. § 456.23. DHS created the Program Integrity and Oversight Division ("PIO") to investigate providers and monitor compliance with federal and state rules, regulations, and statutes governing the health care services provided to patients under the Minnesota Health Care Programs ("MHCP"). ** See Minn. R. 9505.2160,

3

¹ MHCP is an umbrella term that includes all DHS administered health care programs.

subp. 1; Minn. R. 9505.2200, subp. 1. The investigations are necessary to prevent fraud and abuse, as well as to detect instances of improper payment of MA funds due to error. Minn. R. 9505.2200, subp. 1; Minn. R. 9505.2215, subp. 1(A).

III. MINNESOTA'S MEDICAID FRAUD CONTROL UNIT.

The U.S. Secretary of Health and Human Services, acting through the U.S. Office of the Inspector General, and the U.S. Attorney General are required to establish a program to control fraud and abuse with respect to health plans; conduct investigations, audits, evaluations, and inspections relating to the discovery of and payment for health care in the United States; and facilitate enforcement of health care fraud and abuse statutes. *See* 42 U.S.C. § 1320a-7c(a)(1)(A)–(C). This is accomplished by the creation of State Medicaid Fraud Control Units ("MFCU") certified by the Secretary, which possess statewide authority to investigate and prosecute suspected criminal violations relating to the Medicaid program. *See* 42 U.S.C. § 1396b(q); *see also* 42 C.F.R. § 1007.1–1007.21. The MFCU is a separate and distinct entity from DHS. *See* 42 U.S.C. § 1396b(q)(2).

In Minnesota, the MFCU is part of the Attorney General's Office and has authority to prosecute crimes related to Medicaid fraud. *See* Minn. Stat. § 256B.12 (granting authority to the Minnesota Attorney General to prosecute violations of Minnesota Statutes chapter 256B and violations of Minnesota Statutes sections 609.466 and 609.52, subdivision 2). Following PIO investigations, DHS may decide to pursue administrative sanctions and refer the matter to MFCU for criminal investigation.

IV. FEDERAL AND STATE LAW REQUIRE DHS TO TEMPORARILY SUSPEND MEDICAID PAYMENTS BASED ON A CREDIBLE ALLEGATION OF FRAUD.

Under Federal Medicaid regulations, DHS "must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud for which an investigation is pending under the Medicaid program against an individual or entity unless the agency has good cause to not suspend payments or to suspend payment only in part." 42 C.F.R. § 455.23(a)(1) (emphasis added). A "credible allegation of fraud" is defined in federal rule:

A credible allegation of fraud may be an allegation, which has been verified by the State, from any source, including but not limited to the following:

- (1) Fraud hotline complaints.
- (2) Claims data mining.
- (3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

42 C.F.R. § 455.2. DHS must notify the provider of the temporary suspension, id. § 455.23(b), and the notice must:

- (i) State that payments are being suspended in accordance with this provision.
- (ii) Set forth the general allegations as to the nature of the suspension action, but need not disclose any specific information concerning an ongoing investigation.
- (iii) State that the suspension is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which the suspension will be terminated.
- (iv) Specify, when applicable, to which type or types of Medicaid claims or business units of a provider suspension is effective.
- (v) Inform the provider of the right to submit written evidence for consideration by State Medicaid Agency.

(vi) Set forth the applicable State administrative appeals process and corresponding citations to State law.

Id. § 455.23(b)(2).

The temporary suspension of payments—which are commonly referred to as "temporary payment withholds"—must continue until either (a) "[t]he agency or the prosecuting authorities determine that there is insufficient evidence of fraud by the provider," or (b) "[l]egal proceedings related to the provider's alleged fraud are completed." *Id.* § 455.23(c). The temporary suspension of payments, however, does not prohibit a provider from continuing to provide services to anyone, including Medicaid recipients; it simply means DHS will not issue payment until the temporary payment withhold is lifted. (Declaration of Amanda Novak, ¶ 15.) And, of course, nothing about the temporary payment withhold prevents a provider from serving, billing, and receiving payment from non-Medicaid clients. (*Id.*)

Minnesota law is consistent with federal regulations:

Except when the commissioner finds good cause not to suspend payments under Code of Federal Regulations, title 42, section 455.23 (e) or (f), the commissioner *shall* withhold or reduce payments to a vendor of medical care without providing advance notice of such withholding or reduction if either of the following occurs:

- (1) the vendor is convicted of a crime involving the conduct described in subdivision 1a; or
- (2) the commissioner determines there is a credible allegation of fraud for which an investigation is pending under the program. A credible allegation of fraud is an allegation which has been verified by the state, from any source, including but not limited to:
 - (i) fraud hotline complaints;
 - (ii) claims data mining; and

(iii) patterns identified through provider audits, civil false claims cases, and law enforcement investigations.

Allegations are considered to be credible when they have an indicia of reliability and the state agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis.

Minn. Stat. § 256B.064, subd. 2(b). The notice of temporary payment withhold must be sent within five days of DHS's action, and must:

- (1) state that payments are being withheld according to paragraph (b);
- (2) set forth the general allegations as to the nature of the withholding action, but need not disclose any specific information concerning an ongoing investigation;
- (3) except in the case of a conviction for conduct described in subdivision 1a, state that the withholding is for a temporary period and cite the circumstances under which withholding will be terminated;
- (4) identify the types of claims to which the withholding applies; and
- (5) inform the vendor of the right to submit written evidence for consideration by the commissioner.

The withholding or reduction of payments will not continue after the commissioner determines there is insufficient evidence of fraud by the vendor, or after legal proceedings relating to the alleged fraud are completed, unless the commissioner has sent notice of intention to impose monetary recovery or sanctions under paragraph (a).

Id., subd. 2(c).

A. State Law Does Not Provide Hearing Rights For Temporary Payment Withholds.

Federal regulations defer to State law with respect to whether administrative review of a temporary payment withhold is available. *See* 42 C.F.R. § 455.23, subd. (a)(3) ("A provider may request, and must be granted, administrative review where State law so

requires"). Minnesota State law does not provide for such hearings. Section 256B.064 states that:

Except as provided in paragraphs (b) and (d), neither a monetary recovery nor a sanction will be imposed by the commissioner without prior notice and an opportunity for a hearing, according to chapter 14, on the commissioner's proposed action, provided that the commissioner may suspend or reduce payment to an individual or entity . . . after notice and prior to the hearing if in the commissioner's opinion that action is necessary to protect the public welfare and the interests of the program.

Minn. Stat. § 256B.064, subd. 2. Paragraph (b) of subdivision 2 sets forth DHS's payment withhold authority and obligation, providing that the commissioner "shall withhold or reduce payments to an individual or entity" where "there is a credible allegation of fraud for which an investigation is pending." *Id.*, subd. 2(b). And paragraph (d) of subdivision 3 sets forth requirements for how long a payment withhold is to remain in place, which includes "after the commissioner determines there is insufficient evidence of fraud by the individual or entity, or after legal proceedings relating to the alleged fraud are completed, unless the commissioner has sent notice of intention to impose monetary recovery or sanctions under paragraph (a)." *Id.*, subd. 2(d). As it did in this case, DHS allows a provider to submit information if it disagrees and requests that DHS not impose the temporary payment withhold. *Id.*, subd. 2(c)(5); *see also* Doc. 8-1

V. DHS DETERMINES THAT THERE IS A CREDIBLE ALLEGATION OF FRAUD AGAINST NUWAY.

In January 2024, the U.S. Department of Justice ("DOJ") notified DHS's Office of Inspector General ("OIG") of the existence of an active investigation into Nuway and related entities under the federal False Claims Act and Minnesota False Claims Act.

(Novak Decl., \P 2.) DOJ advised DHS OIG that its investigation was being conducted in coordination with the Minnesota Attorney General's Office, with assistance from DHS. (*Id.*) DOJ stated that its investigation to date "indicates that the allegations of fraud against Nuway are credible and bear indicia of reliability." (*Id.*) DOJ provided additional information to DHS regarding the investigation but advised DHS that the information could not be disclosed.² (*Id.*)

Based on information provided by the DOJ, as well as DHS's own independent review and investigation, DHS determined that there was a credible allegation of fraud against Nuway for which an investigation was pending. (Id., ¶ 3.)

VI. NUWAY ADMITS THAT IT IS UNDER INVESTIGATION FOR MEDICAID FRAUD AND HAS ACKNOWLEDGED ENGAGING IN PRACTICES THAT ARE SUBJECT TO THAT INVESTIGATION.

Both in its filings and in public statements, Nuway has confirmed that it is under active investigation for Medicaid fraud. According to Nuway, the DOJ issued a Civil Investigative Demand on April 1, 2022, related to a False Claims Act investigation. (Doc. 12 at 5; Doc. No. 8, \P 2). Nuway acknowledges the subject of the DOJ's investigation includes both alleged kickbacks involved in Nuway's practice of paying for its outpatient treatment clients' housing, as well as alleged fraudulent billing practices. (*Id.*, $\P\P$ 3, 6.) Nuway has also confirmed that it has engaged in conduct that it acknowledges is the subject of that investigation, as have media reports.

9

² Given the nature of the investigation and in accordance with direction from the DOJ, DHS is unable to provide additional information in this filing. However, DHS requests that the Court receive, *in camera*, additional information made available to DHS by the DOJ.

First, in public statements and according to media reports, Nuway admitted it regularly billed overlapping treatment time periods to DHS. According to a media report, Nuway scheduled its clients for 35-minute treatment sessions so that it could bill DHS for an hour of treatment. Ten minutes after that 35-minute session ended, Nuway scheduled its clients for another 35-minute session so that it could bill DHS for another hour of treatment.³ In just 70 minutes, Nuway regularly received reimbursement for two hours of treatment. In its filings in this case, Nuway acknowledges engaging in these practices. (Doc. No. 8, ¶ 22 (acknowledging that Nuway regularly scheduled sessions for 35 minutes, "took short beaks, and then began another session of less than an hour" and then billed for two separate one-hour units "[b]ecause each individual session passed the midpoint").)

While Nuway now claims that its billing is consistent with DHS policy then in existence, it appears its Revenue Cycle Director, Chief Financial Officer, and outside counsel raised concerns about this billing practice:

• According to a KARE 11 report, "[o]n August 11, 2022, Morgan Kluender – NUWAY's Revenue Cycle Director – wrote to CFO John Marston" and "advised 'Knowing that we continue to send duplicative claims out daily, I would advise that we stop sending claims, citing CMS's (Center for Medicare Medicaid Service's) definition of Fraud, Waste, and Abuse..."

³ See https://www.kare11.com/article/news/investigations/kare-11-investigates-overbilling-kickbacks-state-accuses-addiction-treatment-nonprofit-nuway-of-fraud/89-d2daa456-3145-4442-a6df-9d6171470d18 (last visited February 14, 2025).

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• According to that same report, "[t]wo weeks later Marston, NUWAY's CFO, sent an email indicating that legal guidance from the law firm Swanson Hatch – run by former Minnesota Attorneys General Lori Swanson and Mike Hatch – advised 'the practice of always billing just over the minimum required time is problematic," and "recommended NUWAY should 'align programming with the number of hours/units being billed." *Id*.

Second, Nuway admitted that it provided rent subsidies to its clients who received treatment services. (Doc. 1 at ¶¶ 16-17). According to Nuway, it "pays an abstinence-based recovery residence" a \$700 per month stipend each month for individuals who receive intensive outpatient treatment with Nuway. (*Id.* at ¶ 17). According to statements made by the DOJ, it believes housing payments of this kind may constitute illegal kickbacks.⁵

VII. DHS ISSUES TEMPORARY PAYMENT WITHHOLDS TO PLAINTIFFS.

A. February 29, 2024 Notices Of Payment Withhold

On February 29, 2024, DHS issued Notices of Payment Withhold to nine Nuway clinics that provide outpatient treatment services. (Novak Decl., Ex. 1.) The Notices indicated that DHS would withhold MHCP payments to Nuway effective April 1, 2024, because DHS "determined there is a credible allegation of fraud for which an investigation is pending under the MHCP." (*Id.*) Although under state law DHS must only "set forth

https://www.kare11.com/article/news/investigations/kare-11-investigates-overbilling-kickbacks-state-accuses-addiction-treatment-nonprofit-nuway-of-fraud/89-d2daa456-3145-4442-a6df-9d6171470d18 (last visited February 14, 2025).

the general allegations as to the nature of the withholding action, but need not disclose any specific information concerning an ongoing investigation," Minn. Stat. § 256B.064, subd. 2(c), DHS informed Nuway that it had information that Nuway:⁶

- Billed for services not provided as billed;
- Improperly induced services through the use of illegal kickbacks;
- Failed to return overpayments;
- Submitted claims for which it was not entitled to reimbursement; and
- Failed to document services in compliance with legal requirements.

(Novak Decl., Ex. 1.)

The notices informed Nuway it had "the right to submit written evidence to DHS explaining why payments should not be withheld." (*Id.*) Nuway responded, requested that DHS provide additional details regarding the underlying fraud investigation, and asked that DHS not impose the temporary payment withholds because it would result in disruption of care. (Novak Decl., Exs. 7-8.) DHS reviewed the information provided and informed Nuway it would continue with the temporary payment withhold. (Doc. 8-2, Ex. B to Glaser Decl.) DHS further notified Nuway that—consistent with its statutory obligations—it could disclose only general information regarding the nature of the withholding action but could not disclose further specific information regarding ongoing investigations. (*Id.*) DHS reiterated that the payment withholds would only remain in effect until prosecuting

⁻

⁶ Because temporary payment withholds take effect during the pendency of an investigation, it is important that information related to the investigation not be shared, especially with the target of any investigation. It is for this reason that both state and federal law provide that the payment withhold notice "need not disclose any specific information concerning an ongoing investigation." Minn. Stat. § 256B.064, subd. 2(c)(2); 42 CFR § 455.23(b)(2)(ii).

authorities determined there is insufficient evidence of fraud or until legal proceedings related to the alleged fraud are completed. (*Id.*)

In response, Nuway's counsel submitted correspondence urging DHS to not impose the payment withhold because it would be a "Pyrrhic fight" and that withdrawing the payment withhold would be "an easy way out of this fight." (Doc. 8-2, Ex. C to Glaser Decl.) Nuway's counsel acknowledged that he was fully aware of the DOJ's investigation into Nuway and the subjects of that investigation, but contended that DHS should conclude there was no credible allegation of fraud to support the payment withhold. (*Id.*)

B. Temporary Payment Withhold Set To Take Effect February 21, 2025.

DHS provided Nuway with several extensions of the initial effective date of the payment withhold, issuing Amended Notices of Payment Withhold on March 15, 2024, April 15, 2024, and June 13, 2024. (Novak Decl. Exs. 2-4.) These amended notices extended the effective date of the payment withhold to May 15, June 15, and December 16, 2024, respectively. (*Id.*) DHS notified Nuway that its initial extension was provided in order to allow DHS time to complete its review of Nuway's submission and to allow "additional time for Nuway to provide notice to clients and facilitate their transition to new providers [as well as] to allow clients to seek housing subsidies, if necessary, through local social services programs" if the payment withholds were to remain in place. (Doc. 8-4, Glaser Decl. Ex. D.) In each amendment to the temporary payment withhold, DHS provided Nuway the opportunity to "submit written evidence to DHS explaining why payments should not be withheld." (*Id.*) DHS continued to communicate with Nuway and

consider the information and evidence it submitted. Nuway submitted some information additional to what they had sent in response to the initial notice, specifically:

- On October 31, 2024, Nuway submitted an email and documentation in response to DHS's June 13, 2024, Amended Notice of Payment Withhold, scheduled to become effective December 16, 2024. (Doc. 8-4, Glaser Decl. Ex. F);
- On November 21, 2024, DHS responded that it "considered the information contained in your email, as well as the information contained in the investigative file required by Minnesota Statutes, section 256B.064, subdivision 2(b)(2)" and "maintains there is a credible allegation of fraud for which an investigation is pending related to claims submitted by Nuway."

 (Novak Decl. Ex. 6);
- In an email that same day, DHS's Office of Inspector General Chief Legal Counsel Betsy Schollmeier said it was "open to further requests by Nuway for additional time before the payment withhold goes into effect to mitigate a negative impact on clients," but that "DHS, however, is not withdrawing the payment withhold notice." (*Id.*);
- On December 5, 2024, DHS again amended its Notices of Payment Withhold to take effect on February 21, 2025. (Novak Decl. Ex. 5);
- On January 28, 2025, Nuway's counsel, David Glaser, again asked DHS not to effectuate the previously noticed temporary payment withhold on February 21, 2025. (Doc. 8-4 at p. 9, Glaser Decl. Ex. E);

- On January 30, 2025, Mr. Glaser again wrote to DHS asking that it not effectuate the temporary payment withhold. (*Id.* at p. 7);
- On January 31, 2025, Ms. Schollmeier responded and asked to meet "to discuss next steps to ensure client continuity of care." (*Id.* at p. 6);
- On February 3, 2025, Mr. Glaser conveyed his "worr[y] that the call tomorrow may be more about what happens if the payment suspension takes effect." (*Id.* at p. 5);
- Later on February 3, 2025, Ms. Schollmeier responded and said DHS wanted "to understand NUWAY's intentions for its operations in the coming weeks with the payment withhold date looming," and explained "DHS is not entertaining another extension of the payment withhold at this time and is interested in understanding what steps NUWAY is considering to ensure clients can receive care and housing and maintain licensing compliance going forward." (*Id.* at p. 4);
- On February 4, 2025, DHS representatives and NUWAY met with the intention to discuss transitioning affected clients, but Nuway continued to request that DHS withdraw or delay the payment withhold. (Sather Decl., ¶7.)

At no time during any of Nuway's various communications and submissions to DHS from February 2024 through January 2025 did it ever request a contested case hearing on the payment withhold or take the position that it was entitled to such a hearing. (See generally Glaser Decl.; Novak Decl.).

DHS determined that good cause existed to extend the effective date of the payment withholds in order to allow additional time to plan for Nuway recipients to transition to new providers and avoid service disruptions, as well as based on requests from the DOJ to delay implementing the payment withholds while Nuway and the DOJ pursued settlement discussions to resolve the pending False Claims Act investigation and mitigate impact on Nuway's clients. (Novak Decl., ¶ 12.) DHS otherwise preferred to implement the temporary payment withhold given the credible allegations of fraud it was aware of. (Doc. 8-5 at p. 2; see also Novak Decl. ¶ 12). By late January, DHS was informed that those settlement discussions had failed, and DHS determined there was no longer good cause to delay implementation of the payment withholds. (Novak Decl., ¶ 12.) Consistent with the parties' communications, DHS did not extend the temporary payment withhold scheduled to take effect on February 21, 2025. (Id.) The operative Amended Notice of Payment Withhold was issued on December 5, 2024, providing Nuway with 78 days' notice prior to the effective date in which to notify its recipients and assist in transitioning services to other providers if it would no longer provide services after that date. (Novak Decl., Ex. 5.)

VIII. PLANNING FOR POTENTIAL SERVICE DISRUPTIONS FOR NUWAY'S RECIPIENTS.

DHS has been actively working to assess and mitigate any potential impact on Nuway's outpatient SUD recipients from the payment withholds. (Declaration of Jennifer Sather, \P 3). DHS has monitored and analyzed the SUD outpatient provider community's capacity to serve individuals with the counties of current Nuway outpatient SUD programs should there be a service disruption. (*Id.*) DHS believes that existing treatment providers

in Minnesota will be able to absorb the majority, if not all, of Nuway's outpatient SUD recipients if Nuway stops providing those services. (Id., ¶ 4.) Further, Nuway's current outpatient SUD recipients must have a needs assessment performed for any new service provider. (Id., ¶ 5.) Based on the assessed needs of Nuway's current recipients, some recipients may not be appropriate for continued outpatient SUD services, and instead may be appropriate for inpatient SUD services, other types of services, or no services at all. (Id.)

Further, Minnesota law requires that providers like Nuway plan and prepare for ensuring continuity and transfer of care in the event of a program closure. Nuway must have a written plan in place "indicating how the program will ensure the transfer of clients and records for both open and closed cases if the program closes." Minn. Stat. § 245A.04, subd. 15a. This plan must include "specify[ing] arrangements the program will make to transfer clients to another provider or county agency for continuation of services and to transfer the case record with the client." *Id.* Further, Nuway is required to notify affected clients of closure at least 25 days prior to closure, including information regarding how to access their records. *Id.* It does not appear that Nuway has provided this notice to its recipients. (*See generally*, Roberts Decl.; Sather Decl., ¶ 10.)

DHS has also prepared a resource document to be given to Nuway's outpatient SUD recipients who may experience service disruption, which contains various resources for individuals to utilize in obtaining SUD treatment support and housing support services if they experience treatment disruption or housing instability. (Sather Decl., \P 6). DHS provided this document to Nuway and requested that it distribute it to its recipients. (*Id.*)

It does not appear that Nuway has provided this resource document to its recipients. (Roberts Decl., ¶ 20.) Further, DHS requested that Nuway provide a list of its current clients who receive housing subsidies in conjunction with outpatient treatment so that DHS could assist in helping provide housing resources to impacted clients. (Sather Decl., ¶ 7; see also Ex. 1 to Sather Decl.)

IX. NUWAY RECEIVES OVER \$2.8 MILLION IN MHCP REIMBURSEMENT EACH MONTH.

In 2021, Nuway's outpatient treatment programs that are subject to the temporary payment withhold averaged \$ 2,938,955 in MHCP reimbursement each month. (Novak Decl., ¶ 17.) Beginning April 2022 when Nuway became aware it was the subject of a federal False Claims Act investigation by the United States Attorney, Nuway sought \$2,841,849 in reimbursement on average each month through January 2024. (*Id.*, ¶ 18.) Since February 2024 when Nuway was first notified of the payment withholds, its reimbursements have averaged \$2,812,584 per month. (*Id.*)

Despite DHS repeatedly notifying Nuway of the impending payment withholds beginning in February 2024—and urging Nuway of the need to notify its recipients in order to aid in their transition to other providers—Nuway has *increased* the number of recipients to whom it provides outpatient substance use disorder treatment. Since it first received the initial notices of payment withholds in February 2024, Nuway's average number of outpatient SUD service recipients increased by 34%. (*Id.*, ¶ 16.)

LEGAL STANDARD

The same legal standard applies to temporary restraining orders and preliminary injunctions. *Izabella HMC-MF, LLC v. Radisson Hotels Int'l, Inc.*, 378 F. Supp. 3d 775, 777-78 (D. Minn. 2019). "A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). To determine whether to issue a temporary restraining order or preliminary injunction, the district court must consider: (1) the threat of irreparable harm to the movant; (2) the balance between that harm and the injury that granting the injunction will inflict on the other interested parties; (3) the probability the movant will succeed on the merits; and (4) whether the injunction is in the public interest. *Izabella HMC-MF*, 378 F. Supp. 3d at 777-78 (citing *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981)). The party seeking injunctive relief bears the burden of proving all the preliminary injunction factors. *Watkins, Inc. v. Lewis*, 346 F.3d 841, 844 (8th Cir. 2003).

ARGUMENT

I. NUWAY IS NOT LIKELY TO SUCCEED ON THE MERITS.

Nuway does not have a constitutionally protected property or liberty interest in Medicaid payments, as participation in the program is voluntary and does not create an entitlement. Federal and State law mandate the withholding of payments to Medicaid providers when there are credible allegations of fraud. A hearing is not required to withhold payments under such circumstances. Nuway fails to establish a due process violation, as it lacks a property or liberty interest, and the state's interest in preventing fraud outweighs any claimed deprivation. Moreover, the Medicaid Act does not grant providers a private right of action to challenge state compliance, as enforcement authority rests with CMS, not private parties. Consequently, Nuway is not likely to succeed on the merits.

A. NUWAY Does Not Have A Protected Property Interest.

Medicaid providers do not have a constitutionally protected property interest in payments for or on behalf of beneficiaries. Property interests are protected, but not created, by the Constitution. *Bd. of Regents of State Colls. v. Roth*, 408 U.S. 564, 577 (1972). Rather, property interests arise from an independent source, such as a statute or contract "that secure[s] certain benefits and that support[s] claims of entitlement to those benefits." *Id.* A property interest does not arise simply from a party's unilateral expectation of it. *Id.*

To state a procedural due process claim, Nuway must demonstrate: (1) the existence of a constitutionally protected liberty or property interest; and (2) that Defendant deprived it of that interest without constitutionally adequate process. *Kroupa v. Nielsen*, 731 F.3d 813, 818 (8th Cir. 2013); *Schmidt v. Des Moines Pub. Schs.*, 655 F.3d 811, 817

(8th Cir. 2011). The federal Due Process Clause protects only those interests to which a party has a legitimate claim of entitlement. *Town of Castle Rock, Colo. v. Gonzales*, 545 U.S. 748, 756 (2005). To constitute "property" for purposes of the Due Process Clause, a party must have a legitimate claim of entitlement to a given benefit. *Id.* Nuway's mere expectation of receiving the benefit is insufficient. *Id.*

Nuway frames the deprivation of its purported property right as the closure of their businesses. But Nuway does not and cannot allege that DHS required that it close its business. Instead, DHS suspended Nuway's ability to receive reimbursement under the Medicaid program; DHS did not prohibit Nuway from serving customers. Nuway may have structured its business based on the unilateral expectation of continued payments from the Medicaid program, but a financial interest in the program does not give rise to a property interest.

The Minnesota Court of Appeals addressed this very issue in *Shire v. Harpstead*, holding that a provider does not have a protected property interest in Medicaid payments. No. A19-0807, 2019 WL 7287088, at *4 (Minn. Ct. App. Dec. 30, 2019). In so holding, the Court stated:

Nor do appellants have a property interest in Medicaid payments while an investigation is pending. The statute in this case [Minn. Stat. § 256B.064, subd. 2(b)] makes clear that the government retains the power to temporarily suspend payments when there are credible allegations of fraud. Because the statute authorizes payment withholds pending fraud investigations, it confers on appellants no entitlement to the payments during an investigation. Appellants therefore have no protected property interest created by statute.

Id. (citations omitted)

Federal appellate courts that have considered the matter have generally concluded that participation in the Medicaid program as a provider does not create a protected property interest. See, e.g., Erickson v. United States ex rel. Dep't of Health & Human Servs., 67 F.3d 858, 862 (9th Cir. 1995) (holding that provider did not have a property interest in continued participation in Medicare, Medicaid, or other similar programs); Kelly Kare, Ltd. v. O'Rourke, 930 F.2d 170, 175-76 (2d Cir. 1991) (holding that the government reserved vast discretion over the continued participation of parties in Medicaid, and thus the provider had no protected property interest); see also Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare, 742 F.2d 442, 446 (8th Cir. 1984) (holding that a statute imposing rate limits on nursing homes did not violate substantive due process or result in a taking, as participation in the Medicaid program is voluntary).

When a provider like Nuway is under investigation, courts have specifically rejected the claim that a temporary suspension from Medicaid participation pending a fraud investigation implicates a protected property right. *See, e.g., Care Prods., Inc. v. Hawkins*, 635 F.3d 155, 158-59 (5th Cir. 2011) (holding there is no property right in Medicaid reimbursements pending a fraud investigation); *Guzman v. Shewry*, 552 F.3d 941, 953 (9th Cir. 2009) (holding that temporarily suspended provider did not have a property interest in continued Medicaid participation); *cf. Clarinda Home Health v. Shalala*, 100 F.3d 526, 531 (8th Cir. 1996) (noting "[t]he private interest that will be affected by a temporary withholding of Medicare payments is not as serious in nature as an exclusion from the Medicare program").

There is no dispute that Nuway is under investigation for Medicaid fraud. The statute in this case makes clear that the government retains the power to temporarily suspend payments when there are credible allegations of fraud. *See* Minn. Stat. § 256B.064, subd. 2(b); *Shire*, No. A19-0807, 2019 WL 7287088, at *3; *cf. Personal Care Prods., Inc. v. Hawkins*, 635 F.3d 155, 159 (5th Cir. 2011) (observing that "Texas regulations plainly permit" the Medicaid withholding). Nuway's efforts to argue the merits of the underlying fraud are therefore misplaced, as DHS need not prove a substantive fraud claim in order to withhold payments but instead must only determine that a credible allegation of fraud exists. Such a credible allegation may be verified "from any source" including but not limited to information derived from "civil false claims cases, and law enforcement investigations." 42 C.F.R. § 455.2; Minn. Stat. § 256B.064, subd. 2(b). Nuway cannot dispute that such sources exist here.

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⁷ Although not necessary to respond to this motion because it cannot be disputed that DHS determined there is a credible allegation of fraud—which is all that is necessary for a payment hold to be mandated by the law—DHS certainly disputes Nuway's characterization of the underlying conduct that it concedes is subject to a Medicaid fraud allegation. The DHS bulletin Nuway relies on provided that treatment services must last at least 31 continuous minutes in order to qualify for one billable unit of an hour. (Doc. 8–7, p. 5). Nuway twists that minimum requirement into a purported blanket approval of its systematic practice of wringing two billable hours out of 70 actual minutes of treatment time, which it admits it engaged in. Even if it may be acceptable to bill one hour of service when the amount of actual service time is less than an hour—that is, to record a billing hour after serving a client from 2:00-2:45, for example, starting the next billing hour at 3:00—that is a far cry from deriving more than one billing hour from the same hour of actual time. That is exactly what Nuway admits it has done by scheduling its sessions for just over a half hour, taking shorts breaks, and then beginning another session of just over a half hour in order to bill for two separate one-hour units because "each individual session passed the midpoint." (Doc. No. 8, ¶ 22.) Nuway unconvincingly attempts to justify its practice by arguing that a DHS policy did not specifically tell it not to do that.

Because the statute authorizes payment withholds pending fraud investigations, it confers on Nuway no entitlement to the payments during an investigation. Nuway therefore has no protected property interest created by statute. *See The Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972) (no property interest where there is only an abstract need for it or unilateral expectation of it). Moreover, the statute does not impose a time limit, either on the investigation or on the temporary suspension.

Here, Nuway alleges no more than an expectation of continuing to receive Medicaid payments. Nuway's assertion of a property interest here is analogous to a provider's assertion of a property right to a certain reimbursement rate. Appellate courts have long held that Medicaid providers have no property interest in prospective reimbursement rates. Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare, 602 F.2d 150, 153-54 (8th Cir. 1979) (rejecting nursing home's challenge to regulations affecting their reimbursement rate, in part, because "[p]articipation by a nursing home as a provider of health care services to Medicaid recipients is voluntary," and "[i]f appellants find that the reimbursement rates are insufficient, then they may either make their homes more efficient and economical or terminate their relationship with Medicaid and no longer accept Medicaid recipients as residents); see also Sierra Medical Services Alliance v. Kent, 883 F.3d 1216, 1227 (9th Cir. 2018) (rejecting due process claim because "the Plaintiffs voluntarily participate in Medi-Cal and therefore have no constitutionally protected interest in any particular Medi-Cal reimbursement rate."); Managed Pharmacy Care v. Sebelius, 716 F.3d 1235, 1252 (9th Cir. 2013) ("Because participation in Medicaid is voluntary, however, providers do not have a property interest in a particular reimbursement rate.");

Cervoni v. Sec'y of Health, Educ. & Welfare, 581 F.2d 1010, 1018 (1st Cir. 1978) (holding that Medicare provider does not have property interest in continued reimbursements).

Because Nuway is not required to provide services to persons receiving medical assistance, they have no protected property interest.

B. NUWAY Does Not Have A Protected Liberty Interest.

The reasoning above that rejects Nuway's asserted property interest applies with equal force to its asserted liberty interest. In addition to holding that a provider does not have a property interest with respect the withholding of payments under Minnesota Statutes section 256B.064, subdivision 2(b), the *Shire* Court likewise held that a provider does not have a protected liberty interest. Shire, No. A19-0807, 2019 WL 7287088, at *6. The Shire Court explicitly rejected the provider's diminished reputation and stigma argument. Id. *6-7. DHS did not require that the provider's businesses be closed when it withheld Medicaid payments. As with the property-interest analysis, DHS's decision to temporarily withhold payments under the Medicaid statute is not equivalent to a government decision to terminate a business, even if that business relies heavily on Medicaid reimbursements. See Guzman, 552 F.3d at 954-55 (rejecting liberty-interest claim by physician subject to temporary suspension in Medicaid program pending investigation of fraud). Nor are the payment withholds issued by DHS the equivalent of the permanent disqualification of a provider from performing essential job functions. Cf. Fosselman, 612 N.W.2d at 462 (involving permanent disqualification of medical providers from holding direct-contact positions).

Accordingly, Nuway does not have a liberty interest in receipt of Medicaid payment for or on behalf of beneficiaries.

C. State And Federal Law Do Not Require A Hearing.

Federal law requires that state Medicaid agencies suspend all Medicaid payments to a provider upon determining there is a credible allegation of fraud, pending an investigation, unless there is good cause not to suspend payments. 42 C.F.R. § 455.23. The regulation allows the state agency to suspend payments without prior notice to the provider and mandates that the provider be informed of the suspension within five days, unless law enforcement requests a delay. 42 C.F.R. § 455.23. The provider has the right to submit written evidence for consideration and must be informed of the applicable state administrative appeals process, 42 C.F.R. § 455.23, but the regulation itself does not require a contested case hearing before the suspension of payments.

Minnesota law does not provide for a contested case hearing on a temporary payment withhold. Payment suspension is found in Minnesota Statutes, section 256B.064, subdivision 2(b) and (d). Subdivision 2(a), however, makes clear that those actions do not require "prior notice and an opportunity for a hearing." Minn. Stat. § 256B.064, subd. 2(a). ("Except as provided in paragraphs (b) and (d), neither a monetary recovery nor a sanction will be imposed by the commissioner without prior notice and an opportunity for a hearing, according to chapter 14...."). Tellingly, Nuway itself never demanded a contested case hearing in any of its numerous pre-suit communications and submissions to DHS over the course of nearly a year since when it was first notified of the payment withholds,

presumably because it was aware the law does not provide for such a hearing.

(See generally, Glaser Decl.)

The Eighth Circuit's reasoning in *Clarinda Home Health v. Shalala* applies. 100 F.3d 526, 531 (8th Cir. 1996). In *Clarinda*, the court held that a Medicare provider has no due process right to a hearing during an investigation for fraud and misrepresentation. *Id.* As here, *Clarinda* involved a temporary suspension of Medicare payments to the provider during an ongoing investigation for acts of fraud and misrepresentation. The court reasoned that the private interest that will be affected by a temporary withholding of Medicare payments is not serious in nature and did not give rise to a colorable due process claim. *Id.* If temporary withholding of Medicare payments from without a hearing does not give rise to a colorable constitutional due process claim, neither does the same temporary withholding under Medicaid. Both Medicare and Medicaid are cooperative federal-state programs under the Social Security Act. The principles and interpretations established in *Clarinda* are applicable to Medicaid, as they are grounded in the broader framework of the Social Security Act, which governs the Medicaid program. ⁸

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⁸ Nuway also has less of an interest in having its claim resolved than a provider who has been suspended from a program entirely, which also does not require a hearing. *See Anderson v. Sullivan*, 959 F.2d 690, 693 (8th Cir.1992) (the procedures established for excluding a physician from the Medicare program while his appeals were pending did not violate due process); *Peterson v. Weinberger*, 508 F.2d 45 (5th Cir.), *cert. denied*, 423 U.S. 830 (1975) (holding that a Medicare provider has no due process right to a hearing during the course of an investigation for acts of fraud and misrepresentation).

Nuway's alternative argument that Minnesota's statute is unconstitutional if it does not require a hearing is unserious. As discussed above, providers do not have a property or liberty interest in Medicaid reimbursement in any case, and the dimensions of interests protected by procedural due process are defined by state law. Accordingly, where state law

D. Nuway Has Not Demonstrated Likelihood Of Success Under The Mathews Factors.

Even if Nuway could identify a protected liberty or property interest, it cannot demonstrate likelihood of success with respect to the *Mathews* factors for determining the procedural protections to which it is entitled. Courts weigh three factors when determining whether the process provided is adequate: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such interest through the procedure used, and the probable value, if any, of additional or substitute procedural safeguards; and (3) the Government's interest, including the function involved and the fiscal administrative burdens that the additional or substitute procedural requirement would entail. Mathews v. Eldridge, 424 U.S. 319, 332, 334 (1976) ("[D]ue process is flexible and calls for such procedural protections as the particular situation demands."). All three factors weigh against Nuway. As to the first factor, as outlined above, Nuway has neither a property interest nor a liberty interest in the continuation of Medicaid payments while it is under investigation for fraud. Nuway also fails to satisfy the second factor because without a property or liberty interest there is no risk of an erroneous deprivation. Finally, as to the third factor, the State's interest in protecting the integrity of the Medicaid program against fraud and its interest in the administrative process it provides under state law outweigh Nuway's non-existent property and liberty interests.

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specifically provides that a particular benefit may be denied or rescinded with no hearing, procedural due process does not mandate a hearing.

Regardless, DHS provided sufficient process to Nuway for temporary withholding of payments. On February 29, 2024, the Minnesota Department of Human Services (DHS) issued Notices of Payment Withhold to nine Nuway provider numbers, which includes eight outpatient clinics and one consolidated provider number, citing credible allegations of fraud, including billing for services not provided as billed, inducing services through illegal kickbacks, failing to return overpayments, submitting claims for which reimbursement was not entitled, and inadequate documentation of services. (Novak Decl., Ex. 1.) Nuway was informed of its ability to submit written evidence explaining why payments should not be withheld and requested additional details regarding the investigation, expressing concerns about potential disruptions in client care. (Id.) DHS reviewed Nuway's submissions but maintained the payment withhold, citing statutory obligations that limited disclosure of specific information during ongoing investigations. (Doc. 8-2, Ex. B to Glaser Decl.) The payment withhold was initially set to take effect on April 1, 2024, but DHS granted several extensions to allow Nuway time to address the issues and facilitate client transitions as well as for the DOJ and Nuway to pursue settlement discussions. (Novak Decl., Exs. 2-4; Doc. 8-4, Glaser Decl., Ex. D; Doc. 8-5 at p. 2.) Despite ongoing communications and Nuway's requests to withdraw or delay the withhold, DHS determined that there was no good cause to extend the effective date further, and the payment withhold is scheduled to take effect on February 21, 2025. (Novak Decl., Ex. 5.)

E. There Is No Private Right Of Action Under The Medicaid Act.

To enforce any provision of the Medicaid statute under 42 U.S.C. § 1983, Nuway would need to show that the Medicaid statute unambiguously confers providers federal "rights," not simply "benefits" or "interests." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283 (2002). Nuway would also need to "demonstrate that the right assertedly protected by the statute is not so 'vague and amorphous' that its enforcement would strain judicial competence." *Blessing v. Freestone*, 520 U.S. 329, 340-41 (1997). The Supreme Court held that "[t]he question whether Congress ... intended to create a private right of action [is] definitively answered in the negative where a statute by its terms grants no private rights to any identifiable class." *Gonzaga Univ. v. Doe*, 536 U.S. 283–84 (cleaned up).

Irrespective of the underlying alleged basis for its suit, Nuway does not have a private cause of action against DHS under the Medicaid Act. *See Armstrong v. Exceptional Child Center, Inc.*, 575 U.S. 120, 329 (2015). Nuway does not specify in its motion any subsection of the Medicaid Act upon which it relies for authority to assert its cause of action against DHS. Instead, it alleges procedural due process constitutional violations under 42 U.S.C. § 1983. (Doc. 12 at 11, n.3.) Regardless, the Supreme Court's decision in *Armstrong* is instructive. There, the Court considered whether a provider could sue to enforce a subsection of the Medicaid Act. Although the provider in *Armstrong* did not sue under § 1983, the "initial inquiry [for § 1983 purposes]—determining whether a statute confers any right at all—is no different from the initial inquiry in an implied right of action case." *Gonzaga*, 536 U.S. at 285. Therefore, when the *Armstrong* Court determined that the provider had no implied right of action under the Medicaid statute it used the same

analysis that applies under § 1983. The *Armstrong* Court likewise rejected the notion that providers are "beneficiaries of the" general "agreement" between the federal government and the States to implement Medicaid. *Armstrong*, 575 U.S. at 332. The *Armstrong* Court "doubt[ed]" that "providers are intended beneficiaries (as opposed to mere incidental beneficiaries) of the Medicaid agreement, which was concluded for the benefit of the infirm whom the providers were to serve, rather than for the benefit of the providers themselves." *Id.* The Court also explained that "jurisprudence permitting intended beneficiaries to sue does not generally apply" to "contracts between two governments." *Id*; *see also Does v. Gillespie*, 867 F.3d 1034, 1039 (8th Cir. 2017) (holding that section 1396a(a)30(A) does not create a private cause of action under the Medicaid Act).

The Centers for Medicare & Medicaid Services ("CMS") enforces state compliance with the Medicaid statute or state plan, not providers. *See e.g.* 42 U.S.C.A. § 1396c (authorizing the Secretary of Health and Human Services to withhold federal Medicaid payments to a state if, after reasonable notice and opportunity for a hearing, it is found that the state plan no longer complies with the provisions of section 1396a or that there is a substantial failure to comply with any such provision in the administration of the plan;

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⁹ The Declaratory Judgment Act does not create a substantive cause of action, and a declaratory judgment is improper where the underlying statute contains no private right of action. *See, e.g., Schilling v. Rogers*, 363 U.S. 666, 677 (1960) ("[T]he Declaratory Judgment Act is not an independent source of federal jurisdiction; the availability of such relief presupposes the existence of a judicially remediable right."); *Western Cas. & Sur. Co. v. Herman*, 405 F.2d 121, 124 (8th Cir. 1968) (internal citations omitted). Because Nuway has no viable procedural due process or Medicaid Act claim for the reasons above, it cannot separately seek declaratory relief.

42 C.F.R. § 430.35 (providing that CMS may withhold payments if the state plan no longer complies with section 1902 of the Social Security Act or if there is substantial noncompliance in the administration of the plan).

Accordingly, the Medicaid Act does not provide a private right of action for Medicaid providers to sue DHS over temporary payment withholds based on credible allegations of fraud. Enforcement of a state's compliance with Medicaid rests with CMS, not private parties.

II. NUWAY DOES NOT DEMONSTRATE IRREPARABLE HARM TO EITHER ITSELF OR ITS CLIENTS.

Whether alleging harm to itself or its clients, Nuway falls far short of clearing the high bar to show irreparable harm. In any event, however, the equitable doctrine of unclean hands should prevent such a finding.

A. Legal Standard.

To show irreparable harm, "the injury must be both certain and great; it must be actual and not theoretical. Injunctive relief 'will not be granted against something merely feared as liable to occur at some indefinite time'; the party seeking injunctive relief must show that '[t]he injury complained of [is] of such imminence that there is a 'clear and present' need for equitable relief to prevent irreparable harm." *Packard Elevator v. I.C.C.*, 782 F.2d 112, 115 (8th Cir. 1986) (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 673-74 (D.C.Cir.1985)).

"It is also well settled that economic loss does not, in and of itself, constitute irreparable harm. . . . Recoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the [petitioner]'s business." *Id*.

Finally, "[b]are allegations of what is likely to occur are of no value since the court must decide whether the harm will *in fact* occur. The [petitioner] must provide proof that the harm has occurred in the past and is likely to occur again, or proof indicating that the harm is certain to occur in the near future." *Id*.

B. Nuway Does Not Establish It Will Suffer Irreparable Harm.

Nuway says a temporary payment withhold threatens to prevent it from operating and will lead to loss of customer goodwill. But it does not demonstrate irreparable harm on either front.

1. Nuway alleges ordinary economic loss, not the loss of its business.

Nuway relies on case law that the loss of a business may constitute irreparable harm (Doc. 12, p. 16), thus implying it will lose its business without a preliminary injunction. But upon close inspection Nuway does not assert that it will suffer a certain loss of its business, as opposed to a run-of-the-mill economic loss: it claims only that it "will likely be forced to cease intensive outpatient treatment within sixty days." (*Id.* at 15.) But as it makes clear elsewhere, Nuway's intensive outpatient treatment is only a component of its business. Nuway therefore does not claim its "very existence" is threatened, as required. *Packard Elevator*, 782 F.2d at 115.

To the extent portions of Nuway's brief *imply* the entire business is threatened, they cite no supporting evidence. For example, Nuway's brief says that if it "cannot be paid for

the services it provides to Medicaid beneficiaries, it cannot operate," and cites paragraphs 25 through 29 of the Declaration of Kenneth L. Roberts ("Roberts Declaration"). (Doc. 12, p. 15.) But neither those paragraphs, nor any in the declaration's "Impact of Payment Withhold" section say that: the relevant portions make assertions solely about Nuway's intensive outpatient program. (Doc. 9, pp. 10-12 ¶¶ 21-29.) Similarly, Nuway's brief says that "the chances that [its] inpatient residential treatment program can survive without being bolstered by the revenue from Nuway's outpatient treatment program are slim," citing paragraph 29 of the Roberts Declaration. (Doc. 12, p. 15.) But again the cited paragraph simply does not say that, nor does any other part of the declaration. (See Doc. 9.) Absent evidence that Nuway will lose its business, as opposed to sustaining economic loss to a component of its business, Nuway cannot establish irreparable harm. Amigo Gift Ass'n v. Exec. Properties, Ltd., 588 F. Supp. 654, 658 (W.D. Mo. 1984) ("Monetary loss may constitute irreparable harm only where the movant's very existence is threatened, such as where an act threatens an ongoing business with destruction as opposed to mere disruption.").

2. Nuway does not substantiate even the ordinary economic loss it alleges.

Even if Nuway's asserted loss of the intensive outpatient portion of its business were sufficient to demonstrate irreparable harm—which, as discussed above, it is not—Nuway does not provide "proof indicating that the harm is certain to occur in the near future," as required. *Packard Elevator*, 782 F.2d at 115.

Nuway relies entirely on the Roberts Declaration, without any supporting documentation, to substantiate its alleged economic harm. (Doc. 12, pp. 15-16.) But Mr. Roberts says he is Nuway's Chief Clinical Officer, and claims no financial education, experience, or training. (Doc. 9, pp. 1-2.) As the only concrete financial data at issue, Mr. Roberts says that "[a]pproximately sixty-six percent of NUWAY's revenue is generated through its outpatient treatment program, and more than ninety percent of those revenues are from Medicaid-supported payors," suggesting that about 60% of Nuway's revenue 10 comes from Medicaid-supported payors in its outpatient treatment program. (Doc. 9, p. 2 ¶ 5.) While later asserting in conclusory fashion a number of negative effects if this revenue is lost (e.g., Doc. 9, p. 12 ¶ 27-28), Nuway simply provides no financial data or evidence that they will occur. These "[b]are allegations of what is likely to occur are of no value since the court must decide whether the harm will *in fact* occur." *Packard Elevator*, 782 F.2d at 115.

Indeed, the declaration's strongest allusion to evidence of consequences to Nuway's business is a vague statement that Mr. Roberts has "learned it is reasonable to estimate that NUWAY would be forced to cease admissions of new intensive outpatient clients immediately." (Doc. 9, p. 12 ¶ 29.) While this may make sense as to Medicaid-supported intensive outpatient clients, nowhere does Nuway explain its implicit belief that its remaining revenue would be insufficient to allow its outpatient business to continue, much less that it could not shift to private-pay clients or clients using some other non-Medicaid

 $^{^{10}}$.9 x .66 = .594.

funding source. 11 It does not say where Mr. Roberts purportedly "learned" this information, what it means for the estimate to be "reasonable," or why it is reasonable. Simply put, while Nuway may prefer to avoid any disruption of Medicaid reimbursements, it includes almost no actual evidence of the harms it asserts will befall even its outpatient component. Absent such evidence, a preliminary injunction cannot issue. *Packard Elevator*, 782 F.2d at 115.

3. Nuway does not establish irreparable harm from loss of customer goodwill.

Nuway further claims that a temporary payment withhold will cause irreparable harm in the form of lost customer goodwill. (Doc. 12, pp. 16-17.) The Eighth Circuit has held that the alleged loss of customer goodwill is generally compensable through money damages—not irreparable. *Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 895 (8th Cir. 2013) ("[W]e question whether [plaintiff's] alleged injuries, i.e., 'a loss of customers or customer goodwill,' . . . are truly 'irreparable' in the sense that they could not be addressed through money damages if [plaintiff] is successful following a trial on the merits."); *Gen. Motors Corp. v. Harry Brown's, LLC*, 563 F.3d 312, 319 (8th Cir. 2009) ("[W]e conclude that the district court did not clearly err by finding that any lost sales would amount to a compensable injury.").

Nuway cites a single, out-of-circuit case for the proposition that "[t]he loss of goodwill and the impact that loss will have on future business, specifically, is an irreparable

36

¹¹ As noted elsewhere, the temporary payment withhold does not prevent Nuway from providing care, whether to Medicaid or non-Medicaid payor clients; rather the temporary payment withhold pauses Medicaid payments. (Novak Decl., ¶ 15.)

injury for which injunctive relief is appropriate." (Doc. 12, p. 17 (citing *Merrill Lynch*, *Pierce*, *Fenner & Smith Inc. v. Wertz*, 298 F. Supp. 2d 27, 34 (D.D.C. 2002)). But the court in *Merrill Lynch* so held largely because of the specific nature of the investment business at issue, because "it is impossible to calculate the investments that would have flowed from the customers' accounts" should they be lost. 298 F. Supp. 2d at 34. Here, Nuway provides the Court no reason to believe any lost business is not principally calculable and therefore compensable by money damages to the extent otherwise allowed by law—instead essentially taking the unreasonable and legally unsupported position that irreparable harm exists whenever some action threatens to cost a business customers. *Pharm. Care Mgmt. Ass'n v. Tufte*, 297 F. Supp. 3d 964, 982–83 (D.N.D. 2017).

Nor does Nuway provide evidence that any harms it speculates about would be attributable to a payment withhold. As with its other claims of direct harm, Nuway relies entirely on the Roberts Declaration for the alleged loss of customer goodwill. (Doc. 12, p. 17.) But that declaration (aside from the fact that it simply makes unsupported assertions, as discussed above) does nothing to *causally* connect the alleged "[destruction of] the trust patients and partners have placed in NUWAY" (Doc. 9, p. 11 ¶ 26) or alleged already-existing negative effects like decreasing client engagement and staff morale (*id.* at 12 ¶ 28) to DHS, as opposed to (for example) the fact that Nuway has been under a Department of Justice fraud investigation publicized in various media. Such "bare allegations" are insufficient to show irreparable harm. *Packard Elevator*, 782 F.2d at 115.

C. Alleged Harm To Nuway Patients Does Not Support A Finding Of Irreparable Harm.

Nuway otherwise asserts that a temporary payment withhold will harm its patients by depriving them of treatment and housing. While DHS must comply with state and federal law requiring withholding of Medicaid payments while there is a credible allegation of fraud, it is also invested in finding alternative services for Nuway's Medicaid-paying clients. As discussed above, DHS anticipates that existing treatment providers in Minnesota will be able to absorb the majority, if not all, of Nuway's outpatient SUD recipients if Nuway stops providing those services, while some recipients may need a higher or lower level of care. *Supra* at pp. 16-18.

D. The Doctrine Of Unclean Hands Forecloses A Finding Of Irreparable Harm In Any Event.

Even if Nuway had otherwise demonstrated irreparable harm, the Court should decline to find in Nuway's favor on this factor under the doctrine of unclean hands.

"[A] party coming before a court in equity must come with clean hands." Anweiler v. American Elec. Power Serv. Corp., 3 F.3d 986, 993 (7th Cir. 1993).

38

of their housing if DHS put the temporary payment withhold in effect.

¹² NUWAY states that a temporary payment withhold applicable to its outpatient SUD program will also cause clients of that program to lose their Nuway subsidized housing. (Doc. 12, p. 18.) But only the Roberts Declaration attempts to demonstrate that, however, and it only vaguely asserts that he "understand[s] that if Nuway's operations ceased, many Nuway clients in the intensive outpatient program would suffer from two potential changes: interruption of the continuity of treatment and loss of housing," again ignoring Nuway's failure to otherwise even assert, much less substantiate, that its operations will cease, providing no foundation for the statement, and in any event referring to housing loss as merely "potential" for "many" clients. (Doc. 9, p. 10 ¶ 21.) Perhaps most importantly, however, nowhere does Nuway assert or substantiate that it would *have to* kick clients out

"To sustain an unclean hands defense, a defendant must show that the plaintiff has engaged in 'inequitable conduct or bad faith where the misconduct has a material relation to the equitable relief that plaintiff seeks." *Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 533 (S.D.N.Y. 2009) (quoting *Laugh Factory Inc. v. Basciano*, 608 F. Supp. 2d 549, 560 (S.D.N.Y. 2009)). "This equitable doctrine applies to preliminary injunctions." *Boczar v. Kingen*, No. IP 99-0141-C-T/G, 1999 WL 33109074, at *12 (S.D. Ind. July 2, 1999) (citing *Original Great Am. Chocolate Chip Cookie Co. v. River Valley Cookies, Ltd.*, 970 F.2d 273, 281 (7th Cir. 1992)). "[U]nclean hands' really just means that in equity as in law the plaintiff's fault, like the defendant's, is relevant to the question of what if any remedy the plaintiff is entitled to." *Id.* (citing *Polk Bros., Inc. v. Forest City Enter., Inc.*, 776 F.2d 185, 193 (7th Cir.1985)).

A court may decide a preliminary injunction is inappropriate, based on this doctrine, where a plaintiff causes or contributes to the very conditions it claims mandate equitable relief. *See, e.g., Boczar*, 1999 WL 33109074, at *12 ("Thus, the Plaintiffs have created, or at least contributed to, the situation upon which they base their request for a preliminary injunction. In proceeding with the construction and renovation project based on the set of plans submitted to the DMD but not approved by the MSPC, the Plaintiffs acted at their own peril.")

Nuway has done so here. It essentially claims a preliminary injunction should issue due to conditions almost entirely of its own making:

- According to Nuway, it chose to set up the outpatient portion of its business to disproportionately rely on Medicaid-paying clients rather than diversifying funding sources;
- Nuway knew that it was operating under a statute giving DHS the ability to temporarily withhold Medicaid payment upon a credible allegation of fraud;
- Nuway then persistently engaged in highly suspect billing and housing subsidization practices for *two years* after its Revenue Cycle Director, Chief Financial Officer, and outside counsel warned that those practices created a risk of a fraud investigation (*see supra* at pp. 10-11);
- Despite being under fraud investigation for nearly three years, Nuway not only failed to diversify its clients' payments sources but took steps to *increase* the number of Medicaid-paying outpatient clients during that time by about 34%.
 (Novak Decl., ¶ 16);
- Nuway has not cooperated with DHS or provided information that might assist in avoiding disruption of services to its recipients (see Sather Decl., ¶¶ 7-10.)

In sum, even if Nuway had demonstrated that conditions threaten irreparable harm, it has acted both through neglect and affirmatively to create the conditions it complains of. The potential to lose access to payment through a particular insurance provider—even if there were *not* a statute specifically warning a company in Nuway's position of that possibility—is a normal incident of providing healthcare services. The Court should not allow Nuway to manufacture its own crisis in an attempt to circumvent federal and state law preventing Medicaid funds from flowing to companies suspected of fraud.

III. NUWAY HAS NOT ESTABLISHED THAT THE BALANCE OF HARDSHIP OR THE PUBLIC INTEREST MANDATES AN INJUNCTION.

The last two *Dataphase* factors—the balance of hardship and the public interest—do not weigh in favor of Nuway.

As discussed above with respect to the alleged irreparable harm, any hardship to Nuway if an injunction is not granted is either a hardship of its own making or is simply not a protectable interest. Most telling on this point is that Nuway—during the nearly one-year period since it was first notified of the impending payment withholds—has chosen to *increase* the number of recipients its serves rather than even attempt to plan for any disruption of services or assist its recipients in transitioning care. (Novak Decl., ¶ 17; Sather Decl., ¶ 7-10.) Nuway has essentially pursued a "too big to fail" strategy, seeking to escalate the alleged fallout that will result from DHS complying with its obligations to suspend Medicaid payments where there is a credible allegation of fraud. This sort of alleged hardship does not weigh in favor of injunctive relief, nor is it in the public interest to reward—and therefore incentivize in other providers—such conduct.

Similarly, Nuway argues that if the payment withholds take effect, it will "have no ability to pay the government any civil damages." (Br. at 33; see also Doc. 8-3, p. 6 (Nuway counsel's letter to DHS contending that a "payment suspension LOWERS the odds of the state recovering the money" because "[w]ithin two months NUWAY is unlikely to exist . . . [and] the state will receive nothing.").) Essentially, Nuway contends that its Medicaid-supported business has grown so large that the State cannot put a stop to payments even in the face of credible allegations of fraud. According to Nuway, the

government must continue to supply it with Medicaid dollars so that its business might have the ability to repay the government for payments that were improper. But the public interest is not served by ordering the State to pay Nuway with public funds in order to prop up its business so that the State can potentially recover some of those funds one day. This is particularly true given the public reports regarding Nuway's owners and executives taking large salaries, ¹³ while simultaneously claiming that any disruption in Medicaid payments for its outpatient services will cause the business to close its doors immediately.

And in contrast to Nuway's self-imposed hardship, the State of Minnesota would be harmed if it is barred from protecting public funds and carrying out its legal obligations to suspend Medicaid payments. *See Maryland v. King*, 567 U.S. 1301, 1303 (2012) ("[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury" (*quoting New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977)); *Planned Parenthood Minn., N.D., S.D v. Rounds*, 530 F.3d 724, 733 (8th Cir. 2008) (recognizing the need for "an appropriately deferential analysis" before "thwart[ing] a state's presumptively reasonable democratic processes").

Finally and relatedly, the public interest stands squarely on the side of denying Nuway's requested relief. "Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law." *Heckler v. Cmty. Health*

13 1

¹³ https://www.kare11.com/article/news/investigations/kare-11-investigates-overbilling-kickbacks-state-accuses-addiction-treatment-nonprofit-nuway-of-fraud/89-d2daa456-3145-4442-a6df-9d6171470d18 (last visited February 14, 2025).

Servs. Of Crawford County, Inc., 467 U.S. 51, 62-63 (1984) (rejecting argument that government could not recoup Medicare funds due to harm to provider's operations, noting that "the expansion of [provider's] operation was achieved through unlawful access to government funds" and "those who deal with the Government are expected to know the law"). Further, Minnesota law mandates that DHS "shall endeavor to . . . prevent the waste or unnecessary spending of public money." Minn. Stat. § 245.03, subd. 2(1). And Minnesota law directs that the State must "comply with federal [Medicaid] requirements in order to receive the maximum amount of federal funds which are available." Minn. Stat. § 256B.041, subd. 4. Enjoining DHS from complying with its clear and unambiguous statutory obligations to suspend Medicaid payments when there is a credible allegation of fraud would contravene the public interest and deprive the State of one of its primary tools to combat Medicaid fraud.

IV. IF NUWAY IS GRANTED A TEMPORARY INJUNCTION, IT MUST POST A BOND.

The Court should require Nuway to post an injunction bond pursuant to Fed. R. Civ. P. 65(c) if it grants Nuway's requested relief. Rule 65(c) mandates the posting of security if preliminary relief is granted:

The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.

Fed. R. Civ. P. 65(c). The amount of an injunction bond is a discretionary decision of the Court. *Stockslager v. Carroll Elec. Co-op. Corp.*, 528 F.2d 949, 951 (8th Cir. 1976).

In this case, Nuway seeks to enjoin DHS from protecting Medicaid funds by temporarily suspending payments to Nuway for outpatient substance use disorder treatment. If DHS is enjoined from suspending these payments to Nuway, it expects that Nuway will continue to seek reimbursement of approximately \$2.8 million a month in Medicaid funds until such time as all legal proceedings and appeals relating to the underlying conduct may conclude. (Novak Decl., ¶ 19.)

CONCLUSION

Based on the foregoing, the Court should deny NUWAY's motion in full.

Dated: February 15, 2025 Respectfully submitted,

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