

1 Jason D. Guinasso (Nevada Bar No. 8478)  
 Devon T. Reese (Nevada Bar No. 7496)  
 2 Alex Velto (Nevada Bar No. 14961)  
 HUTCHISON & STEFFEN, PLLC  
 3 5371 Kietzke Lane  
 Reno, Nevada 89511  
 4 Telephone: (775) 853-8746  
 Facsimile: (775) 201-9611  
 5 [dreese@hutchlegal.com](mailto:dreese@hutchlegal.com)  
[avelto@hutchlegal.com](mailto:avelto@hutchlegal.com)  
 6 [jguinasso@hutchlegal.com](mailto:jguinasso@hutchlegal.com)

7 Nina Spizer (*Pro Hac Vice Forthcoming*)  
 Silvio Trentalange (*Pro Hac Vice Forthcoming*)  
 8 DILWORTH PAXSON LLP  
 1500 Market Street, Ste. 3500E  
 9 Philadelphia, PA 19102  
 Telephone: (215) 575-7000  
 10 Facsimile: (215) 575-7200  
[nspizer@dilworthlaw.com](mailto:nspizer@dilworthlaw.com)  
 11 [strentalange@dilworthlaw.com](mailto:strentalange@dilworthlaw.com)

12 *Attorneys for Plaintiff Donor Network West*

13 **UNITED STATES DISTRICT COURT**

14 **DISTRICT OF NEVADA**

15 DONOR NETWORK WEST, a non-profit  
 corporation,

16 Plaintiff,

17 vs.

18 NEVADA DONOR NETWORK, INC, a non-  
 19 profit corporation, NEVADA DONOR  
 NETWORK FOUNDATION, INC, a non-profit  
 20 corporation and RENOWN HEALTH, a non-  
 profit corporation,

21 Defendants.

Case Number:

22 **VERIFIED CIVIL COMPLAINT**

**DEMAND FOR JURY TRIAL**

23 Plaintiff DONOR NETWORK WEST (“DNW”), a California-based non-profit  
 24 corporation, by and through its undersigned counsel, hereby brings this action against Defendants  
 25

1 NEVADA DONOR NETWORK, INC. and NEVADA DONOR NETWORK FOUNDATION,  
2 INC. (collectively referred to herein as “NDN”), and RENOWN HEALTH (“Renown Health”),  
3 all of which are Nevada non-profit corporations. DNW is informed and believes, and based  
4 thereon alleges, as follows:

5 **INTRODUCTION**

6 1. This case involves Defendants NDN and Renown Health working to prevent  
7 Plaintiff DNW from performing its federally mandated organ donation services in DNW’s  
8 federally designated organ-donation service area in northern Nevada (the “Northern Nevada  
9 DSA”).

10 2. Plaintiff DNW is a non-profit organ procurement organization (“OPO”) federally  
11 designated and required to serve Reno, NV and the surrounding Northern Nevada DSA. In short,  
12 DNW works to recover, preserve, transport, and facilitate the donation of organs for life-saving  
13 transplant.

14 3. Defendant NDN is an OPO based in Las Vegas, NV and is designated under  
15 federal law to serve only hospitals located in the southern Nevada donation service area (the  
16 “Southern Nevada DSA”).

17 4. Recognizing it will never surpass DNW in organ-donation recovery efficiency and  
18 competency, Defendant NDN has resorted to unfair tactics to unsettle DNW’s relationships in the  
19 Northern Nevada DSA with organ donation and recovery stakeholders.

20 5. For the last ten years, NDN has taken steps to break into the Northern Nevada  
21 DSA and disrupt DNW’s ability to recover organs.

22 6. In this respect, NDN has made misrepresentations and engaged in misconduct to  
23 create confusion and unrest among DNW and affiliated hospital employees, and to disrupt the  
24 flow of organ donations throughout the Northern Nevada DSA to needy patients, including  
25 Nevadans awaiting life-saving transplant procedures.

1 7. DNW has served northern Nevada for close to 40 years and has longstanding  
2 relationships with area hospitals, medical providers, and the community at-large.

3 8. DNW accordingly has a longstanding relationship with Defendant Renown Health  
4 and has worked closely with its flagship hospital, the Renown Health Regional Medical Center,  
5 and with two of its other facilities, Renown South Meadows Medical Center d/b/a Renown  
6 Rehabilitation Hospital and Renown South Meadows Medical Center, in the Reno metropolitan  
7 area.

8 9. DNW and Renown Health memorialized this relationship in an Affiliation  
9 Agreement.

10 10. Strangely, despite never complaining of any material shortcomings, quality or  
11 competency issues for years, on September 29 and October 23, 2023, Renown Health sent DNW  
12 notice it was unilaterally cancelling its federally mandated Affiliation Agreement with DNW  
13 without cause, effective January 4, 2024.

14 11. Upon information and belief, Renown Health breached and noticed termination of  
15 the Affiliation Agreement with Plaintiff DNW, only after Defendant NDN offered Renown  
16 Health \$3 million in seed money for a new organ transplant program, an offer predicated on  
17 Renown Health naming NDN its new OPO.

18 12. Upon information and belief, the \$3 million NDN offered Renown Health came  
19 through an award NDN obtained via American Rescue Plan Act (“ARPA”) funds from the State  
20 of Nevada.

21 13. There is no practical or lawful reason for why NDN demanded its disbursement of  
22 federal ARPA funds be predicated on NDN obtaining a federally based organ procurement  
23 agreement from Renown Health.

24 14. Upon information and belief, NDN’s offer and demand violated the Anti-Kickback  
25 Statute (42 U.S.C. § 1320a-7b), and upends the longstanding federal public policy fostering the

1 orderly recovery, preservation, and transport of donated organs by specific designated OPOs and  
2 other non-profits under federal law and regulations.

3 15. In this connection, on September 11, 2023, Renown Health indeed applied for a  
4 required waiver from the U.S. Centers for Medicare & Medicaid Services (“CMS”) to designate  
5 NDN as Renown Health’s new OPO.

6 16. CMS, however, has not granted nor is expected to grant soon any of Renown  
7 Health’s requested waivers allowing NDN to be Renown Health’s new OPO in the Northern  
8 Nevada DSA.

9 17. This is a problem because Renown Health is remarkably terminating the  
10 Affiliation Agreement with Plaintiff DNW—its federally designated OPO in the Northern Nevada  
11 DSA—despite having no legal ability to work with any other OPO for organ donation and  
12 recovery services in the Northern Nevada DSA.

13 18. Put differently, when Renown Health effectuates termination of the Affiliation  
14 Agreement on January 4, 2024 (as it represented to DNW), Renown Health will be refusing to  
15 work with its federally designated OPO prior to CMS determining whether DNW can be replaced  
16 by NDN.

17 19. Renown Health consequently intends to refuse to work with its legally designated  
18 OPO to serve its donors and to recover organs to save the lives of others, an untenable situation  
19 that will cause both Renown Health and DNW to violate federal law.

20 20. Further, should Defendant NDN attempt to recover organs in Renown Health’s  
21 facilities without a CMS OPO waiver in place, it too will be operating outside of federal law.

22 21. Upon information and belief, NDN and Renown Health’s brazen misconduct  
23 causing this OPO hole in the Northern Nevada DSA could put organ transplant patients at grave  
24 risk.  
25

1 22. NDN's unlawful inducement of Renown Health improperly interfered with  
2 DNW's Affiliation Agreement, and Renown Health breached that Agreement when it unlawfully  
3 and unilaterally terminated the Agreement without cause and for an illegal purpose.

4 23. These actions have damaged DNW, threaten to damage DNW by rendering  
5 impossible its ability to comply with federal law, and threaten the health and well-being of  
6 Nevadans on the organ-transplant waiting list by harming the process surrounding the donation  
7 and recovery of organs in Northern Nevada.

8 24. Plaintiff DNW thus brings this Complaint to protect itself from further harm at the  
9 hands of NDN and Renown Health.

10 25. DNW accordingly seeks injunctive and monetary relief against Defendants  
11 Renown Health and NDN.

12 **PARTIES**

13 **Plaintiff**

14 26. Plaintiff Donor Network West is a non-profit 501(c)(3) organization formed under  
15 the laws of California with its registered office address at 12667 Acosta Blvd., Ste. 500, San  
16 Ramon, CA 94583.

17 27. DNW is also a registered non-profit corporation in Nevada and maintains an office  
18 at 5440 Reno Corporate Drive, Reno, NV 89511.

19 28. DNW is a designated OPO under federal law committed to helping save and heal  
20 lives by supporting donor families and engaging in education and community outreach to  
21 advocate organ donation as a fundamental human responsibility.

22 29. DNW connects organ, eye, and tissue donors with people in need of life-saving  
23 transplant. DNW also provides education to hospital staff and community partners on the organ  
24 referral and donation process and offers a strong network of support for the courageous donor  
25 families who save lives through the gift of organ donation.

1 30. DNW is the federally designated OPO for the Northern Nevada DSA.

2 31. In that respect, DNW is legally obligated to serve hospitals and health care  
3 providers in the counties of Washoe, Carson City, Douglas, Mineral, Churchill, and Humboldt  
4 Counties as the designated OPO. *See* 42 U.S.C. § 273(a)-(b)(1), (3).

5 32. The counties of Washoe and Carson City were originally designated to the DSA  
6 that DNW serves, but DNW is also responsible to serve the counties of Douglas, Mineral,  
7 Churchill and Humboldt Counties as the hospitals in those counties sought, and were granted,  
8 waivers from CMS to work with DNW in lieu of remaining with the Southern Nevada DSA. NDN,  
9 the Southern Nevada DSA, does not have authorization to recover organ donors in those four  
10 counties where the CMS hospital waivers were granted.

11 33. DNW is the nation's third largest OPO serving more than 13 million people by  
12 connecting organ, eye, and tissue donors to transplant recipients not only in the forty-five counties  
13 geographically interconnected throughout Northern Nevada and Northern California, but also on  
14 the national transplant wait list.

15 **Defendants**

16 34. Defendant Renown Health is a Nevada non-profit organization with a principal  
17 address at 1155 Mill Street N-11, Reno, NV 89502.

18 35. Renown Health operates one of Nevada's largest health systems with more than  
19 13,000 health care providers statewide.

20 36. Renown Health offers a Level II Trauma Center at Renown Regional Medical  
21 Center.

22 37. Renown Regional Medical Center is Renown Health's flagship hospital, and is  
23 located in Reno, NV.

24 38. Renown South Meadows Medical Center d/b/a Renown Rehabilitation Hospital  
25 and Renown South Meadows Medical Center are also located in Reno, NV.

1 39. These three Renown Health facilities fall within DNW’s Northern Nevada DSA,  
2 and DNW is currently their designated OPO under federal law.

3 40. Defendant Nevada Donor Network, Inc., is a non-profit 501(c)(3) organization  
4 formed under the laws of Nevada with a principal address at 2055 E. Sahara Ave., Las Vegas,  
5 NV 89104.

6 41. NDN is the federally designated OPO for the Southern Nevada DSA and serves  
7 donor hospitals specific to that geographic area, except for certain hospitals that work with DNW  
8 per the above-noted and explained below CMS OPO waiver.

9 42. On information and belief, NDN recovers the vast majority of its organ donations  
10 from a single county, Clark County.

11 43. Defendant Nevada Donor Network Foundation, Inc., (“NDN Foundation”) is a  
12 non-profit 501(c)(3) organization formed under the laws of Nevada with a principal address at  
13 2055 E. Sahara Ave., Las Vegas, NV 89104.

14 44. Upon information and belief, NDN Foundation is a supporting organization to  
15 NDN and focuses on funding and creating a full-scale transplant institute in Nevada.

16 **JURISDICTION AND VENUE**

17 45. This Court has original subject matter jurisdiction over this action and these parties  
18 pursuant to 28 U.S.C. § 1331 because, DNW’s claims arise under federal law including the Public  
19 Health Service Act, 42 U.S.C. §§ 201 *et seq.* (which includes the at-issue National Organ  
20 Transplant Act, , *et seq.*) and the Social Security Act of 1935, 42 U.S.C. §§ 1138 *et seq.*, and  
21 accompanying regulations at, Breac.

22 46. This Court also has original subject matter jurisdiction over this action and these  
23 parties pursuant to 28 U.S.C. § 1332, because complete diversity of citizenship exists between  
24 the parties in this action and the amount in controversy exceeds \$75,000.00, exclusive of interest  
25 and costs.

1 47. This Court has personal jurisdiction over Defendants because Defendants are  
2 incorporated and/or have their principal place of business in Nevada, and because Defendants’  
3 alleged misconduct that harmed DNW occurred in Nevada.

4 48. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b), because  
5 Defendants are subject to personal jurisdiction in this district and/or a substantial part of the events  
6 or omissions giving rise to this action occurred in this district.

7 **FACTUAL ALLEGATIONS**

8 **A. The Applicable Statutory and Regulatory Framework**

9 49. “In the United States, organ transplants are a public-private affair.” *Callahan v.*  
10 *U.S. Dep’t of Health and Human Servs.*, 939 F.3d 1251, 1254 (11th Cir. 2019).

11 50. Congress established a national organ transplant infrastructure in 1984 by enacting  
12 the National Organ Transplant Act of 1984, Pub. L. 98-507, 98 Stat. 2339 (Oct. 19, 1984)  
13 (codified as amended at 42 U.S.C. §§ 273 *et seq.*) (“NOTA”).

14 51. NOTA directs the Secretary of Health and Human Services (“HHS”) to register  
15 qualified OPOs and to designate only one registered and qualified OPO for each DSA throughout  
16 the country. 42 U.S.C. § 273(a)-(b)(1).

17 52. Under NOTA, a qualified OPO is required to, among other things, recover,  
18 preserve, allocate equitably, transport, and distribute, donated organs from its respective DSA in  
19 facilitation of organ transplant procedures. *Id.* at § 273(b)(1), (3).

20 53. Toward this end, NOTA requires each OPO to have effective agreements with a  
21 substantial majority of the hospitals in its designated DSA that have organ donation facilities  
22 and/or programs. *Id.* at § 273(b)(3)(A).

23 54. An OPO accordingly develops relationships and protocols with the hospitals  
24 operating within its respective designated DSA coverage area. *Id.*

25 55. Correspondingly, the Social Security Act of 1935 (the “SSA”) requires Medicare



1 and Medicaid participating hospitals that conduct organ recovery or transplants to have an  
2 exclusive agreement with the OPO in their DSA. 42 U.S.C. § 1320b-8(a)(1)(C). Regulations  
3 further require that, “[u]nless CMS has granted a hospital a waiver . . . the hospital *must* enter into  
4 an agreement *only* with the OPO *designated* to serve the area in which the *hospital is located*.”  
5 42 CFR § 486.308(a) (emphasis added).

6 56. Thus, only one OPO operates in a DSA and a hospital in a DSA may contract with  
7 only one OPO—the CMS designated OPO to serve that hospital, absent the existence of a waiver  
8 that has been granted to a hospital by CMS. *Id.*

9 57. This above-described organ donation federal regulatory regime has been in place  
10 for decades, and ensures that the OPO working with an organ donor decedent’s family in a DSA  
11 is free from profit or competitive motivation, and that its service fees are tied to actual cost.

12 58. Although the OPO/DSA framework is based on metropolitan service areas, and  
13 not political boundaries, the SSA does permit a hospital to work with an OPO outside its DSA,  
14 but only under limited circumstances and upon receiving a waiver from CMS. *Id.* at § 1320b-  
15 8(a)(2)(A), (B); *see also* 42 CFR § 486.308(e).

16 59. To obtain an OPO waiver, the requesting hospital must demonstrate to CMS that:  
17 (i) the waiver is expected to increase organ donation; and (ii) the waiver will assure equitable  
18 treatment of patients referred for transplants within the service area served by such hospital’s  
19 designated organ procurement agency, and within the service area served by the organ  
20 procurement agency with which the hospital seeks to enter into an agreement under the waiver.  
21 *Id.*

22 60. CMS may consider other factors such as cost effectiveness and quality  
23 improvements in granting an OPO waiver request. *Id.*

24 61. In making an OPO waiver request, the SSA requires the requesting hospital to  
25 submit an application to CMS, after which, CMS shall: (i) publish a public notice of any waiver

1 application received from a hospital within 30 days of receiving such application; and (ii) prior  
2 to making a final determination on such application offer interested parties the opportunity to  
3 submit written comments to CMS during the 60-day period beginning on the date such notice is  
4 published. *Id.*

5 62. Thus, the shortest time prescribed for CMS action on an OPO waiver request is 61  
6 days from receipt of a hospital's application. *Id.*

7 63. Here, CMS published Renown Hospital's OPO waiver request to designate NDN  
8 as its new OPO on November 24, 2023. *See* Medicare and Medicaid Programs; Announcement  
9 of Application From a Hospital Requesting Waiver for Organ Procurement Service Area,  
10 *available at* [https://www.federalregister.gov/documents/2023/11/24/2023-25904/medicare-and-](https://www.federalregister.gov/documents/2023/11/24/2023-25904/medicare-and-medicaid-programs-announcement-of-application-from-a-hospital-requesting-waiver-for)  
11 [medicaid-programs-announcement-of-application-from-a-hospital-requesting-waiver-for](https://www.federalregister.gov/documents/2023/11/24/2023-25904/medicare-and-medicaid-programs-announcement-of-application-from-a-hospital-requesting-waiver-for) (Nov.  
12 24, 2023).

13 64. The public comment period thus ends on January 23, 2024. *Id.*

14 65. Moreover, upon information and belief, CMS has not acted on any U.S. hospital's  
15 OPO waiver application since 2014.

16 66. Notably, upon information and belief, CMS granted its last OPO waiver  
17 application in 2014, waiving in DNW to serve several hospitals in the Southern Nevada DSA  
18 (Defendant NDN's designated territory).

19 **B. DNW Is Renown Health's Designated OPO in the Northern Nevada DSA**

20 67. DNW is the designated qualified OPO for the Northern Nevada DSA under federal  
21 law.

22 68. This designation is memorialized in an agreement between DNW and CMS. *See*  
23 Exhibit 1 (the "CMS Agreement").

24 69. DNW has been the sole OPO in the Northern Nevada DSA for over forty years.

25 70. CMS and DNW most recently renewed the CMS Agreement on May 9, 2022. *Id.*

1           71.     The CMS Agreement provides DNW with the exclusive right to conduct organ  
2 recovery, preservation, allocation and transportation activities in the Northern Nevada DSA. *Id.*

3           72.     The CMS Agreement, and the federal regulatory regime described above, requires  
4 DNW to contract with any Medicare and Medicaid participating hospital engaged in organ  
5 recovery or transplant procedures in its Northern Nevada DSA. *Id.*; *see also* 42 U.S.C. § 1320b-  
6 8(a)(1)(C).

7           73.     The CMS Agreement thus entirely governs organ donation services for Medicare  
8 and Medicaid participating entities in the Northern Nevada DSA.

9           74.     The Northern Nevada DSA includes Defendant Renown Health’s flagship hospital,  
10 Renown Regional Medical Center, Renown South Meadows Medical Center d/b/a Renown  
11 Rehabilitation Hospital, and Renown South Meadows Medical Center, all of which are located in  
12 Reno, NV.

13           75.     On this background, DNW and Renown Health have been parties to an Affiliation  
14 Agreement for over forty years. *See* Exhibit 2 (the “Affiliation Agreement”).

15           76.     This Agreement states DNW and Renown Health will work together to recover,  
16 preserve, and transport donated organs and tissue for transplantation, or research when  
17 transplantation is not possible. *Id.*

18           77.     In addition to the parties’ roles and responsibilities, the Affiliation Agreement also  
19 provides:

1           10. **Termination:** This Agreement may be terminated by either party only upon the occurrence  
2 of one or more of the following circumstances:

3           a. Decertification by the CMS of Donor Network West as the designated organ  
4 procurement organization for Hospital;

5           b. Upon designation of another organ procurement organization by the CMS to be  
6 Hospital's designated organ procurement organization;

7           c. Upon the granting of a waiver to Hospital by the CMS to work with another organ  
8 procurement organization; or

9           d. Upon a showing by Hospital that it is no longer subject to compliance with any  
10 federal or state regulation requiring that it refer potential organ and tissue donors to any organ  
11 procurement organization.

12           This agreement shall stand as a document without expiration. Either party desiring to  
13 terminate this Agreement in response to any of the aforesaid circumstances or without cause shall  
14 provide as reasonable notice as is possible, but in no case less than ninety (90) days' written notice  
15 to the other party. Such notice shall specifically state the reason for termination of the Agreement,  
16 and such party desiring to terminate this Agreement shall provide such documentation to the other  
17 party supporting the reason so stated.

18 *Id.*

19           78. To date, none of the relevant conditions precedent in the Affiliation Agreement –  
20 Section 10(a)-(d) have occurred.

21           **C. Defendants NDN and Renown Health Sabotaged and Disrupted Plaintiff  
22 DNW's Organ Donation Operations in the Northern Nevada DSA**

23           79. A main purpose of the governing federal organ donation system is to transcend  
24 geographic and political boundaries to match donated organs with recipients as quickly as  
25 possible.

          80. DNW therefore works with every hospital in its Northern Nevada DSA, as well as  
with other Nevada-based institutions such as the University of Nevada (Reno School of Public  
Health), the Nevada Hospital Association, Donate Life Nevada, and other Nevada health and  
community-based organizations.

          81. DNW also recently established the Northern Nevada Advisory Council, which is  
comprised of Northern Nevada community leaders and stakeholders in its mission.

1 82. In the past five years, DNW, which is the third largest OPO in the nation, increased  
2 organ donation in the Northern Nevada DSA and surrounding area by 46% from the previous  
3 decade.

4 83. In 2022, DNW had the highest donation rate in Nevada of any OPO operating in  
5 Nevada.

6 84. DNW, accordingly, has invested considerable infrastructure costs and other  
7 resources to enhance organ donation accessibility in the Northern Nevada DSA, including but not  
8 limited to, an ongoing expansion of highly trained and educated staff in the Northern Nevada  
9 DSA and a substantial increase in office space in Reno, NV.

10 85. Defendant NDN is the federally designated OPO for the Southern Nevada DSA  
11 and is headquartered in Las Vegas, NV, about 435 miles from the Northern Nevada DSA, DNW's  
12 Reno Office, and Renown Regional Medical Center.

13 86. More so, DNW's California office, along with the numerous transplant centers that  
14 serve Nevada residents, are approximately 217 miles away from Renown Regional Medical  
15 Center—i.e., half the distance from NDN's Las Vegas headquarters.

16 87. Although the above-described federal OPO/DSA organ donation framework  
17 intends to curb unnecessary and unfair competition between OPOs, upon information and belief,  
18 NDN has worked to infiltrate the Northern Nevada DSA and sabotage and disrupt DNW's  
19 relationship with Renown Health and other healthcare systems.

20 **1. NDN's Past Attempts to Infiltrate the Northern Nevada DSA**

21 88. Key to NDN's attempted intrusion into the Northern Nevada DSA includes, upon  
22 information and belief, NDN's repeated representation to Renown Health that NDN and/or its  
23 affiliated supporting organization, Defendant NDN Foundation, and its project the Nevada  
24 Transplant Institute, will fund, build, and then jointly operate with Renown Health an organ  
25 transplant center in or around Reno, NV.

1 89. Neither NDN nor any OPO in the United States is qualified or permitted to operate  
2 a transplant center. Transplant services are hospital functions requiring specific approval from  
3 CMS, in accordance with federal law, regulations, and membership in the Organ Procurement  
4 Transplantation Network (“OPTN”). Simply put, OPOs recover organs; they do not transplant  
5 them.

6 90. Upon information and belief, in 2019, NDN’s CEO, Joseph Ferreira, represented  
7 to Renown Health’s then CEO, Dr. Tony Slonim, that NDN would fund a transplant center in the  
8 Reno metropolitan area and would work together with Renown Health on both organ donation  
9 and transplant operations at the transplant center.

10 91. NDN was not then, and is not now, permitted to recover donated organs in the  
11 Northern Nevada DSA.

12 92. Upon information and belief, NDN was motivated to infiltrate the Reno  
13 metropolitan area and DNW’s Northern Nevada DSA on the understanding that doing so would  
14 increase NDN’s margins/revenue by 40%.

15 93. Upon information and belief, Chris Bosse, Renown Health’s Chief Government  
16 Relations Officer *and* a NDN board member, fostered the NDN-Renown Health relationship.

17 94. Upon information and belief, Ms. Bosse has served on the NDN board of directors  
18 since 2010, despite her employer, Renown Health, not working with NDN due to both the  
19 Affiliation Agreement between DNW and Renown Health, and federal law prohibiting NDN from  
20 providing organ donation services to Renown Health.

21 95. Upon information and belief, Renown Health had great interest in working with  
22 NDN on this transplant center project, but the COVID-19 pandemic outbreak in early 2020  
23 interrupted further developments.

24 //

1                   **2.     NDN Receives \$15 Million in ARPA Funding and Plans to Open the**  
2                   **Nevada Transplant Institute in DNW’s Northern Nevada DSA**

3                   96.     On October 22, 2022, NDN announced it received \$15 million in ARPA funds  
4 from the State of Nevada, one of the largest amounts awarded to a single non-profit organization  
5 by the Interim Finance Committee to date.<sup>1</sup>

6                   97.     These funds were earmarked specifically to support the creation of the Nevada  
7 Transplant Institute (“NTI”), which, upon information and belief, intends to collaborate with  
8 NDN, academic institutions, hospitals, payers, transplant centers, and community health care  
9 providers in a singular, dedicated network to expand transplantation programs and services  
10 throughout Nevada.

11                  98.     In May 2023, NDN CEO, Joseph Ferriera, incorporated the NTI and is listed as its  
12 President, Secretary, Treasurer, and Director.

13                  99.     On May 11, 2023, it was reported that NDN intends to build the NTI in Reno, NV,  
14 within DNW’s Northern Nevada DSA.<sup>2</sup>

15                  100.    This is a laudable goal but has nothing to do with an OPO’s fundamental function  
16 of recovering donated organs, except that without a stable source of organs effectively and  
17 lawfully recovered by an authorized OPO, there will be fewer organs to transplant.

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21                  <sup>1</sup> Press Release, *Amount is one of the largest ARPA allocations awarded to a single*  
22 *nonprofit in the state to date*, Las Vegas Heals (Oct. 22, 2022), available at  
23 [https://www.lasvegasheals.org/nevada-donor-network-awarded-15-million-in-american-rescue-](https://www.lasvegasheals.org/nevada-donor-network-awarded-15-million-in-american-rescue-plan-act-funds-from-state-of-nevada-to-establish-nevada-transplant-institute/)  
24 [plan-act-funds-from-state-of-nevada-to-establish-nevada-transplant-institute/](https://www.lasvegasheals.org/nevada-donor-network-awarded-15-million-in-american-rescue-plan-act-funds-from-state-of-nevada-to-establish-nevada-transplant-institute/); see also Green  
and DeSilva, *Nevada Donor Network closer to opening statewide transplant institute*, KNPR  
(Oct. 31, 2022), available at [https://knpr.org/show/knprs-state-of-nevada/2022-10-31/nevada-](https://knpr.org/show/knprs-state-of-nevada/2022-10-31/nevada-donor-network-closer-to-opening-statewide-transplant-institute)  
[donor-network-closer-to-opening-statewide-transplant-institute](https://knpr.org/show/knprs-state-of-nevada/2022-10-31/nevada-donor-network-closer-to-opening-statewide-transplant-institute).

25                  <sup>2</sup> Bond, *Transplant Center coming to Northern Nevada*, KOLO ABC 8 (May 11, 2023),  
available at <https://www.kolotv.com/2023/05/11/transplant-center-coming-northern-nevada/>.

1 101. To be clear, success of any future transplant services in Nevada does not depend  
2 on and is not tied to NDN providing OPO donation services in the Northern Nevada DSA.

3 102. If NDN builds the NTI in the Northern Nevada DSA, DNW is still obligated under  
4 federal law to serve it as that area's designated OPO.

5 103. Further, given DNW's superior donation and recovery rates compared to NDN's,  
6 it is safe to say any new transplant program developed in the Northern Nevada DSA will be best  
7 served by DNW.

8 104. A press release from NDN stated its transplant centers—one in Reno and one in  
9 Las Vegas—would be open and operational by October 2023. This representation was wildly  
10 optimistic, given that a transplant program must also receive CMS and OPTN approval, neither  
11 of which, on information and belief, NDN has applied for. *See* 42 CFR §§ 488.20, 488.61.

12 **3. NDN and Renown Health Re-Engage Transplant Center Discussions**  
13 **and Move to Force DNW Out of the Northern Nevada DSA**

14 105. Upon information and belief, around December 2022, NDN again approached  
15 Renown Health about its participation in operating the NTI to be built in Reno, NV.

16 106. Upon information and belief, NDN offered Renown Health \$3 million as an  
17 inducement to terminate its affiliation with DNW and to engage NDN as its OPO in the Northern  
18 Nevada DSA.

19 107. Around this time, DNW, in its usual course of business, tried numerous times  
20 without success to meet with Renown Health's new CEO, Dr. Brian Erling.

21 108. Dr. Erling, however, refused to meet DNW's CEO until the Mayor of Reno  
22 intervened to convene a meeting.

23 109. On or about May 9, 2023, DNW CEO, Janice Whaley, and others, met with  
24 Renown Health CEO, Dr. Brian Erling, and discussed DNW's role as the federally designated  
25 OPO in the Northern Nevada DSA.



1 110. Upon information and belief, Ms. Whaley and Dr. Erling also discussed NDN's  
2 plans to build the NTI in Reno and Renown Health's partnership with NDN in operating the NTI.

3 111. Upon information and belief, during this meeting Dr. Erling explained that  
4 Renown Health faced financial difficulties and informed DNW of the \$3 million forthcoming  
5 from NDN in connection with the NTI project.

6 112. Upon information and belief, Dr. Erling then asked Ms. Whaley whether DNW  
7 could provide Renown Health any resources.

8 113. Ms. Whaley responded informing Dr. Erling that DNW could not offer Renown  
9 Health any financial funding for an organ transplant center.

10 114. Upon information and belief, Dr. Erling responded that Renown Health's decision  
11 concerning using NDN or DNW as its OPO depended on Renown Health's best financial interest.

12 115. Any promise or payment of money or thing of value made in return for arranging  
13 any service for which payment may be made by a federal healthcare program, violates the federal  
14 Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b)).

15 116. Further, if any non-profit OPO promised or gave such payment to Renown Health,  
16 it would also violate its obligations as a non-profit organization under state law and as a Medicare  
17 contractor under federal law.

18 117. DNW also believes such promise and/or payment would create a system of  
19 exchanging monetary value for the referral of potential organ donors, which is in opposition to  
20 public policy prohibiting the exchange of valuable consideration for transplantable human organs.

21 118. On or about August 29, 2023, representatives and stakeholders from Reno city  
22 government met with Renown Health, NDN, and DNW representatives.

23 119. Upon information and belief, during this meeting NDN presented about the NTI  
24 project in Reno, NV.

25

1 120. Upon information and belief, during this meeting Renown Health advocated for  
2 NDN to become its OPO in the Northern Nevada DSA.

3 121. Upon information and belief, during this meeting DNW advised that Renown  
4 Health had no legitimate basis to seek an OPO waiver to designate NDN as the new OPO for  
5 Renown Health in the Northern Nevada DSA.

6 122. Upon information and belief, around the time of this meeting NDN began  
7 contacting other hospitals and medical providers in the Northern Nevada DSA suggesting they  
8 apply for OPO waivers to work with NDN, considering the supposed impending commencement  
9 of the NTI in Reno.

10 123. On information and belief, NDN told a Northern Nevada DSA hospital that  
11 continuing to work with DNW violated Medicare regulations. NDN's claim is false.

12 124. In the above-described meetings and, upon information and belief, in  
13 communications and numerous public statements before community members and stakeholders,  
14 NDN repeated misrepresentations that: (1) the NTI's transplant program requires that NDN be  
15 the sole OPO serving all Nevada hospitals; and (2) that the NTI's transplant program will increase  
16 the number of Nevada citizens receiving organ transplants.

17 125. NDN's assertions are incorrect because they do not comport with federal law or  
18 the corresponding organ, recovery, allocation, and distribution framework.

19 **4. Renown Health Seeks CMS OPO Waiver to Use NDN and Unilaterally**  
20 **Terminates Its Affiliation Agreement with DNW**

21 126. On or about September 11, 2023, Renown Health applied to CMS for an OPO  
22 waiver, seeking to walk away from DNW and use NDN as its new OPO moving forward. *See*  
23 Exhibit 3 (Renown Health CMS OPO Waiver Request).

24 127. On or about November 24, 2023, CMS opened the 60-day public comment period  
25 on Renown Health's OPO waiver application. *See* Medicare and Medicaid Programs;

1 Announcement of Application From a Hospital Requesting Waiver for Organ Procurement  
2 Service Area, *available at* [https://www.federalregister.gov/documents/2023/11/24/2023-](https://www.federalregister.gov/documents/2023/11/24/2023-25904/medicare-and-medicaid-programs-announcement-of-application-from-a-hospital-requesting-waiver-for)  
3 [25904/medicare-and-medicaid-programs-announcement-of-application-from-a-hospital-](https://www.federalregister.gov/documents/2023/11/24/2023-25904/medicare-and-medicaid-programs-announcement-of-application-from-a-hospital-requesting-waiver-for)  
4 [requesting-waiver-for](https://www.federalregister.gov/documents/2023/11/24/2023-25904/medicare-and-medicaid-programs-announcement-of-application-from-a-hospital-requesting-waiver-for) (Nov. 24, 2023).

5 128. Moreover, on information and belief, CMS last granted an OPO waiver application  
6 in 2014, although hospitals around the country have since then submitted waiver applications that  
7 CMS published. CMS, nevertheless, has not ruled on any of those applications over the last  
8 several years.

9 129. To date, CMS has not decided Renown Health's OPO waiver application and  
10 cannot do so under the regulatory scheme prior to closing the public comment period on January  
11 24, 2024. *Id.*

12 130. Upon information and belief, CMS will then likely take time to consider said  
13 public comments, and more time to draft and issue its ruling on Renown Health's OPO waiver  
14 application.

15 131. It is likewise unlikely that CMS will make a determination on Renown Health's  
16 OPO waiver request prior to ruling on previously submitted waiver requests from other health  
17 care facilities, several of which have been pending for several years.

18 132. More materially, upon information and belief, Renown Health has no plausible  
19 basis to obtain a CMS OPO waiver because any waiver for NDN to serve as its OPO will not  
20 increase organ donations or assure equitable treatment of transplant list patients in the Northern  
21 Nevada DSA. *See* 42 U.S.C. § 1320b-8(a)(2)(A), (B); *see also* 42 CFR § 486.308(e).

22 133. Indeed NDN's performance in the recovery of organs for transplant pales in  
23 comparison to DNW.

24 134. The OPTN is a public-private partnership that links all professionals involved in  
25 the United States organ donation and transplantation system. The OPTN's public partners include

1 HHS and the Health Resources and Services Administration. *See* OPTN, About – OPTN,  
2 <https://optn.transplant.hrsa.gov/about/> (last visited Dec. 7, 2023).

3 135. Consistent with its mission, OPTN collects, catalogues, and assesses certain data  
4 metrics concerning OPO performance. *See* OPTN, Metrics,  
5 <https://optn.transplant.hrsa.gov/data/dashboards-metrics/optn-metrics/> (last visited Dec. 7, 2023).

6 136. Upon information and belief, Defendant NDN lags behind Plaintiff DNW on every  
7 OPTN performance metric for services performed in Nevada.

8 137. For the past decade, DNW’s Nevada operations have maintained the best OPTN  
9 performance and success rating of any Nevada OPO.

10 138. For example, DNW’s OPTN kidney recovery/discard rate for the past four years  
11 was well below the national average and the best of any Nevada OPO.

12 139. Upon information and belief, in the kidney donation context, NDN trails expected  
13 organ yield national standards, and in 2021 and 2022 NDN had the worst kidney discard rate  
14 nationally (discard rate reflects recovered but unused organ donations. OPOs seek to limit discard  
15 rates to avoid waste of valuable resources and high costs).

16 140. Upon information and belief, DNW procures and provides more transplanted  
17 organs per capita than any Nevada OPO.

18 141. What is more, DNW’s kidney procurement costs are lower than any other Nevada  
19 OPO.

20 142. Recognizing it would never surpass DNW in efficiency and competency, NDN  
21 resorted to unfair and improper tactics and, for the last several years, engaged in misrepresentative  
22 misconduct to sabotage DNW’s relationships in the Northern Nevada DSA, create confusion and  
23 unrest among DNW and affiliated hospital employees, and disrupt the flow of organ donations  
24 throughout the Northern Nevada DSA.  
25

1 143. Nevertheless, because CMS has not issued a determination on Renown Health's  
2 OPO waiver application, DNW remains Renown Health's presently designated Northern Nevada  
3 DSA OPO under federal law.

4 144. Yet, despite never complaining of any material shortcomings or quality and  
5 competency issues by DNW, Renown Health advised DNW in letters sent on September 29 and  
6 October 23, 2023, it was unilaterally cancelling its federally mandated Affiliation Agreement with  
7 DNW without cause, effective January 4, 2024. *See* Exhibit 4 (9/29/23 Termination Letter),  
8 Exhibit 5 (10/23/23 Termination Letter).

9 145. In its Sept. 29, 2023 Termination Letter, Renown Health stated, "[t]he reason for  
10 the termination is that Renown is partnering with a Nevada-based donor network." Exhibit 4.

11 146. Such reason is not a legitimate basis nor an enumerated reason for termination  
12 under Affiliation Agreement Section 10. *See* Exhibit 2 (Affiliation Agreement) at Sec. 10.

13 147. Renown Health's Termination Letters also failed to satisfy the Affiliation  
14 Agreement's notice requirements provided in Section 15. *Id.* at Sec. 15.

15 148. Besides violating the Affiliation Agreement, Renown Health is also at odds with  
16 governing federal law, because even if Renown Health obtains an OPO waiver, CMS cannot issue  
17 such waiver prior to January 24, 2024, considering that the 60-public comment period does not  
18 end until January 23, 2024.

19 149. Meaning, Renown Health will be operating without a federally designated OPO  
20 for at least 20-days, which would impede organ donations, thereby putting organ transplant  
21 patients at grave risk.

22 150. On October 19, 2023, DNW responded to Renown Health's Sept. 29, 2023  
23 Termination Letter advising, among other things, that Renown Health's unilateral termination  
24 violated the Affiliation Agreement, was inconsistent with controlling federal law, and caused  
25

1 disruption and uncertainty within the organ and tissue donor community. *See* Exhibit 6 (10/19/23  
2 DNW Response Letter).

3 151. DNW further asked Renown Health to reconsider and disavow its unilateral  
4 Affiliation Agreement termination. *Id.*

5 152. Renown Health replied on October 23, 2023, noting it disagreed with DNW’s  
6 reading of the Affiliation Agreement – Section 10 (Termination) and that its unilateral termination  
7 of the contract without cause was justified. Exhibit 5 (10/23/23 Termination Letter).

8 153. Renown Health also informed DNW for the first time that it applied for an OPO  
9 waiver from CMS on September 11, 2023, and anticipated that CMS would grant the waiver  
10 request within 90 days (i.e. no later than December 10, 2023). *Id.*

11 154. Although Renown Health noted its disagreement and asserted it could terminate  
12 the Affiliation Agreement “without cause,” Renown Health attached an email chain to its Oct. 23,  
13 2023 Termination Letter undercutting its position. *See id.* at 8/8/19 Winter Email to Olson;  
14 8/30/19 Olson Email to Whaley.

15 155. Renown Health’s former CEO, Erik Olson, indeed acknowledged that the  
16 Affiliation Agreement’s 90-day “without cause” termination notice language, “would likely only  
17 apply to the tissue and eyes services, *as CMS designates OPO.*” *Id.* (emphasis added).

18 156. Notably, tissue and eye recovery services are not governed by the same federal  
19 regulatory regime as organ recovery services carried out by designated OPOs.

20 157. Renown Health therefore understands it cannot terminate the Affiliation  
21 Agreement with DNW without cause for organ recovery services because DNW is Renown  
22 Health’s CMS designated OPO.

23 158. Renown Health’s repudiation of the Affiliation Agreement as it applies to DNW’s  
24 OPO serves in the Northern Nevada DSA without cause is thus improper, because none of the  
25

1 triggering termination conditions in Affiliation Agreement, Section 10 – Termination have  
2 occurred.

3 159. Although Renown Health’s termination of the Affiliation Agreement effectuates  
4 on January 4, 2024, it has already taken noticeable actions negatively impacting DNW’s ability  
5 to perform its federally mandated OPO organ donation and recovery services.

6 160. Renown Health recently cancelled several meetings with DNW about organ  
7 recovery, donation, and transplants.

8 161. Renown Health’s recent uncooperative nature has caused confusion among DNW  
9 and Renown Health staff and management involved with organ recovery, donation, and transplant  
10 operations.

11 162. The confusion caused by Renown Health’s sabotage is dangerous as it could result  
12 in the loss of a donated organ or organs for transplant. A single organ donor can save as many as  
13 eight lives.

14 163. All told, DNW understands that Renown Health intends for its unilateral  
15 Affiliation Agreement termination to go into effect as of January 4, 2024, even though CMS  
16 cannot legally grant the CMS OPO waiver by that date, before the sixty-day public comment  
17 period expires.

18 164. At such time, Renown Health—the owner and operator of the largest hospital in  
19 Northern Nevada—will not be legally connected with any federally designated OPO in the  
20 Northern Nevada DSA, thus limiting the supply for the national organ donor list and jeopardizing  
21 the smooth provision of donated organs to many Nevadans and others that so desperately need a  
22 transplant.

23 165. The loss of Renown Health as a participating OPO hospital in the Northern Nevada  
24 DSA is timed purposely to cause disruption and harm to not only donors and transplant recipients,  
25 but also DNW’s standing as the Northern Nevada DSA OPO.

1 166. As Defendant NDN well knows, 2024 is the year in which CMS will gauge  
2 performance metrics of all OPOs nationally, and comparatively. *See* 85 FR 77898-01 (December  
3 2, 2020 Final Rule).

4 167. CMS plans to collect and analyze this OPO performance data to make OPO tier-  
5 level determinations in the future, which could mean that a designated OPO can lose its entire  
6 DSA if it loses even a single potential donor or transplanted organ.

7 168. Indeed, if DNW loses this hunger game scenario due to disruption and confusion  
8 sown by NDN, NDN could take DNW and the Northern Nevada DSA over entirely.

9 169. In short, NDN's aim in sabotaging DNW at Renown Health and in the Northern  
10 Nevada DSA is not to serve Nevadans, but to acquire territory. Rather than collaborate with DNW  
11 to accomplish a lifesaving goal, NDN hopes to weaken DNW's strong performance to serve its  
12 own territorial goals, even as organ donation processes inevitably suffers.

13 **5. NDN Furthers Disruption and Causes Confusion in the Northern**  
14 **Nevada DSA**

15 170. NDN has also furthered disruption and caused confusion in the organ donation  
16 community in the Northern Nevada DSA.

17 171. Upon information and belief, over the past ten years, NDN made public  
18 misrepresentations concerning its status as a federally designated OPO in the Northern Nevada  
19 DSA, and misled numerous stakeholders and hospitals—including Renown Health—about  
20 NDN's ability to provide organ donation services in the Northern Nevada DSA.

21 172. More recently, upon information and belief, NDN created confusion by misleading  
22 Renown Health and DNW employees via leaked false statements claiming NDN will be  
23 Renown's Northern Nevada DSA OPO as of January 1, 2024.

24 173. These statements led many to believe Renown Health obtained a CMS OPO  
25 waiver to work with NDN when it has not.



1 174. Tellingly, Renown Health staff members who were engaged in crucial meetings  
2 regarding organ donation quality and protocols queried whether they should even work with  
3 DNW on continuous improvement initiatives, given their understanding that DNW would soon  
4 no longer be Renown Health's OPO in the Northern Nevada DSA.

5 175. Upon information and belief, Renown Health cancelled meetings with DNW on  
6 the basis it believed NDN would assume DNW's organ recovery, allocation, transport and  
7 donation role and responsibilities as outlined in the Affiliation Agreement.

8 176. In this respect, upon information and belief, Renown Health staff members  
9 verbally informed DNW employees that they understood DNW's Affiliation Agreement  
10 terminated no later than January 2024.

11 177. More so, upon information and belief, at an international organ donor conference  
12 in October 2023, NDN's CEO falsely represented that NDN is the sole Nevada OPO.

13 178. NDN's misrepresentation upset DNW staff present at the conference and caused  
14 insecurity.

15 179. NDN's misrepresentation also confused the broader organ donation and transplant  
16 community present, whose collaboration is essential for the organ donation and transplant system  
17 to work effectively and efficiently.

18 180. In this way, NDN diminished years of DNW's work establishing trusting  
19 relationships with Northern Nevada DSA hospitals—like Renown Health—to foster a fully  
20 synchronized organ recovery, donation, and transplant system to serve the maximum transplant  
21 recipients.

22 181. Additionally in October 2023, NDN held a Job Fair at Atlantis Resort in Reno,  
23 NV, and advertised for Reno-based organ-related job openings.

1 182. Upon information and belief, NDN posted flyers seeking job applicants at  
2 hospitals in DNW’s Northern Nevada DSA in full sight of current DNW employees and hospital  
3 personnel with whom they work, causing confusion, job insecurity and disruption.

4 183. Thus, in addition to interfering with DNW’s relationships with Northern Nevada  
5 DSA hospitals and stakeholders, NDN interfered with DNW’s internal staff and operations.

6 184. Upon information and belief, in October 2023, NDN representatives approached  
7 DNW employees about applying for NDN jobs serving Renown Health.

8 185. Also in October 2023, NDN posted online solicitations seeking organ recovery  
9 employees for positions in the Northern Nevada DSA.

10 186. Further, upon information and belief, in November 2023, Renown Health  
11 instructed its staff to stop collaborating with DNW in providing support for the National  
12 Celebration of Organ Donation event held during the Rose Bowl Parade on or about January 1,  
13 2024.

14 187. NDN’s interference and Renown Health’s disengagement from DNW denies  
15 Reno-donor families and Renown Health patient/organ recipients the opportunity to participate  
16 in a nationwide celebration of their Northern Nevada community and generosity.

17 **6. NDN’s Caused Disruption and Chaos at Renown Health Violates CMS**  
18 **Guidance Governing Waiver and Transition of OPOs and Harms the**  
**Public Interest**

19 188. CMS guidance exists concerning the orderly transition of OPOs in a DSA; a  
20 framework in place to protect the public interest.

21 189. CMS guidance indeed notes that, “[o]utside an approved waiver process, a hospital  
22 may not terminate its agreement with its designated OPO,” and that a hospital may request to  
23 work with an OPO in another DSA, but that a hospital may not terminate its agreement with its  
24 designated OPO until a waiver is granted. *See* X-014, Guideline § 482.74(a)(2), CMS State  
25 Operations Manual, Appendix X – Guidance to Surveyors: Organ Transplant Programs.

1 190. Further, CMS guidance recommends that applicants to become an OPO to a new  
2 DSA via waiver must submit a transition plan. *See* 2812.4, CMS State Operations Manual,  
3 Publication #100-07.

4 191. An incoming OPO to a new DSA must also “submit a monthly summary to the  
5 CMS RO to report on its transition activities. The CMS RO will monitor the transition process to  
6 ensure successful oversight and management of OPO operations.” CMS State Operations 2812.7;  
7 *see also* CMS State Operations Manual, Publication #100-07.

8 192. CMS issues this guidance to ensure the smooth, safe, and orderly substitution of  
9 one OPO for another, especially considering the complex interplay between OPO, hospital, organ  
10 donor, and organ transplant recipient.

11 193. Defendants NDN and Renown Health continue to disrupt any smooth and orderly  
12 transition of OPOs in the Northern Nevada DSA (assuming CMS grants Renown Health’s OPO  
13 waiver application, which is unlikely).

14 194. For example, NDN’s recent attempts to poach DNW employees stationed at  
15 DNW’s Reno office for organ recovery jobs with NDN in Reno has caused insecurity in DNW  
16 employees, leaving them unsure whether they will continue to have jobs with DNW after Renown  
17 Health’s January 4, 2023 Affiliation Agreement termination date.

18 195. This uncertainty has also spread to Renown Health employees, who have recently  
19 cancelled important organ recovery and donation quality-outcome meetings with DNW  
20 employees, under the assumption DNW will no longer be Renown Health’s OPO as of early  
21 January 2024.

22 196. Lack of DNW employee job security and retention, and lack of Renown Health’s  
23 cooperation and coordination with DNW concerning organ recovery efforts, indeed harms every  
24 organ donation/recovery cases and puts organ donation recipients at risk of missing a viable organ  
25 donation for transplant.

1 197. More so, if CMS denies Renown Health’s OPO waiver application, which is likely,  
2 the relationships and efficiencies DNW and Renown Health have developed over time are likely  
3 to be damaged as a result of turnover and ongoing confusion.

4 198. CMS regulations naturally favor orderly OPO transitions at a hospital in event of  
5 CMS waiver.

6 199. Renown Health’s unilateral repudiation and termination of the Affiliation  
7 Agreement on January 4, 2024, overrides CMS’s guidance proceeds along a reckless timeline.

8 200. Renown Health’s ongoing refusal to engage collaboratively with DNW on routine  
9 matters and NDN’s active disruption in the DNW/Renown Health relationship, stand in stark  
10 contrast to the highly involved transition preparations necessary to transfer OPO services safely.

11 201. The lack of any coordinated or planned exchange of services indicates NDN’s  
12 intent to undermine DNW by any means necessary, and without consideration of the clear risk  
13 the chaos it caused poses to the public.

14 **7. NDN Improperly Interfered with the DNW/CMS Agreement**

15 202. The CMS Agreement and federal law and regulations mandate DNW serve as the  
16 sole Northern Nevada DSA OPO, wherein Renown Health’s flagship hospital, Renown Health  
17 Regional Medical Center, is located.

18 203. NDN, on the other hand, is the designated Southern Nevada DSA OPO.

19 204. In this respect, upon information and belief, as the Southern Nevada DSA OPO,  
20 NDN fully understands the legal obligations and requirements between an OPO and a hospital in  
21 its DSA—that is, absent a CMS OPO waiver, only one OPO in a DSA can serve that hospital.

22 205. Despite this knowledge, NDN misled the organ donation community and illegally  
23 offered payment to Renown Health to usurp the Renown Health Affiliation Agreement from  
24 DNW.  
25

1 206. NDN facilitating Renown Health's unilateral Affiliation Agreement termination  
2 effectively places DNW in breach of its separate CMS Agreement.

3 207. To qualify as an OPO under federal law, DNW requires designation to a defined  
4 service area, which in turn requires that all hospitals working with DNW its in service are and are  
5 assigned to the OPO and verified by CMS. *See* Exhibit 1 (CMS Agreement); *see also* 42 C.F.R.  
6 §§ 486.302, 486.304, 486.306.

7 208. Naturally, DNW advised CMS it serves Renown Health.

8 209. Renown Health's unlawful termination and breach of the Affiliation Agreement  
9 due to NDN's interference thus makes DNW's representation to CMS inconsistent and arguably  
10 noncompliant with the CMS Agreement and governing federal regulations.

11 210. NDN therefore improperly interfered with DNW's CMS Agreement.

12 **FIRST CLAIM FOR RELIEF**  
13 **(Breach of Contract Against Defendant Renown Health)**

14 211. Plaintiff DNW hereby incorporates the preceding allegations as if set forth fully  
15 herein.

16 212. The Affiliation Agreement between DNW and Renown Health is a valid and  
17 binding contract for which each party received adequate consideration.

18 213. DNW performed all its obligations under the Affiliation Agreement and Renown  
19 Health is not excused from performing its obligations.

20 214. Renown Health breached the Affiliation Agreement when it unlawfully,  
21 unilaterally terminated the Affiliation Agreement without cause forcing DNW and Renown  
22 Health into noncompliance with federal law.

23 215. As a direct and proximate result of Renown Health's breach of the Affiliation  
24 Agreement, DNW has suffered and will continue to suffer harm and real damages.  
25

1 216. Renown Health’s breach was knowing, willful and malicious, entitling Plaintiff  
2 DNW to exemplary damages.

3 217. Further, Renown Health unilaterally terminated the Affiliation Agreement with  
4 DNW without having any other service agreement with any other qualified OPO assigned to the  
5 Northern Nevada DSA.

6 218. Renown Health’s conduct violated federal law, including NOTA, the SSA, and  
7 accompanying federal regulations. *See* 42 U.S.C. § 273(b)(3)(A); *see also* 42 U.S.C. § 1320b-  
8 8(a)(1)(C); 42 CFR § 482.45.

9 219. Plaintiff DNW therefore requests this Court declare, pursuant to 28 U.S.C. § 2201,  
10 that Defendant Renown Health’s unilateral termination of the Affiliation Agreement violates  
11 controlling federal law and is therefore void, and that the Affiliation Agreement establishing  
12 DNW as Renown Health’s exclusive OPO in the Northern Nevada DSA remains in effect, until  
13 CMS approves, if ever, Renown Health’s OPO waiver application.

14 **SECOND CLAIM FOR RELIEF**  
15 **(Breach of Implied Covenant of Good Faith and Fair Dealing**  
16 **Against Defendant Renown Health)**

17 220. Plaintiff DNW hereby incorporates the preceding allegations as if set forth fully  
18 herein.

19 221. “Every contract imposes upon each party a duty of good faith and fair dealing in  
20 its performance and enforcement.” *A.C. Shaw Constr. v. Washoe County*, 105 Nev. 913, 914, 784  
21 P.2d 9 (1989). “The implied covenants of good faith and fair dealing impose a burden that require  
22 each party to contract to refrain from doing anything to injure the right of the other to receive the  
23 benefits of the agreement.” *Shaw v. CitiMortgage, Inc.*, 201 F. Supp. 3d 1222, 1251 (D. Nev.  
24 2016) (internal citation and quotations omitted).

25 222. The Affiliation Agreement between DNW and Renown Health is a valid and  
binding contract for which each party received adequate consideration.

1 223. Renown Health breached its duty of good faith and fair dealing when it unlawfully,  
2 unilaterally terminated the Affiliation Agreement without cause forcing DNW and Renown  
3 Health into noncompliance with federal law.

4 224. As a direct and proximate result of Defendant Renown Health's breach of good  
5 faith and fair dealing, DNW has suffered and will continue to suffer harm and real damages.

6 225. Renown Health's breach was knowing, willful and malicious, entitling Plaintiff  
7 DNW to exemplary damages.

8 **THIRD CLAIM FOR RELIEF**  
9 **(Intentional/Tortious Interference with Contractual and/or Prospective Business**  
10 **Relationships Against Defendants NDN and NDN Foundation)**

11 226. Plaintiff DNW hereby incorporates the preceding allegations as if set forth fully  
12 herein.

13 227. The Affiliation Agreement between DNW and Renown Health is a valid and  
14 binding contract for which each party received adequate consideration.

15 228. Upon information and belief, Defendant NDN had knowledge of the Affiliation  
16 Agreement between DNW and Renown Health.

17 229. Upon information and belief, Defendant NDN committed myriad intentionally  
18 wrongful acts intended or designed to disrupt DNW's Affiliation Agreement with Renown Health  
19 and its overall working relationship with Renown Health, including but not limited to:

- 20 i. Repeating false representations to Renown Health that NDN and/or  
21 its affiliated supporting organization, Defendant NDN Foundation,  
22 will fund, build, and then jointly operate with Renown Health an  
23 organ transplant center in or around Reno, NV, with the condition  
24 that NDN act as its OPO;
- 25 ii. Offering Renown Health \$3 million to partner with NDN in  
operating the Nevada Transplant Institute ("NTI") in Reno, NV,  
provided that Renown allow NDN to serve as its OPO;
- iii. Falsely announcing before community members and stakeholders  
that NDN's NTI transplant program requires NDN be the sole OPO

1 serving Nevada hospitals, and that the NTI's transplant program will  
2 increase the number of Nevada citizens receiving organ transplants;

- 3 iv. Misleading Renown Health and DNW employees via leaked false  
4 statements claiming NDN will be Renown Health's designated  
5 Northern Nevada DSA OPO as of January 1, 2024;
- 6 v. Falsely representing to an international organ donor conference that  
7 NDN is the sole Nevada OPO;
- 8 vi. Wrongly soliciting job applicants for positions at Northern Nevada  
9 DSA hospitals despite those hospitals not having a CMS OPO  
10 waiver to work with NDN in the Northern Nevada DSA; and
- 11 vii. Approaching DNW employees about applying for NDN jobs  
12 serving Northern Nevada DSA hospitals despite those hospitals not  
13 having a CMS OPO waiver to work with NDN in the Northern  
14 Nevada DSA.

15 230. NDN had no justification to commit these intentionally wrongful acts.

16 231. Upon information and belief, as a result of NDN's intentionally wrongful acts,  
17 which included offering funds in exchange for a federal contract, Renown Health breached the  
18 provisions contained in the Affiliation Agreement by unlawfully, unilaterally terminating the  
19 Agreement without cause.

20 232. Prospective contractual relationships exist or existed between DNW and other  
21 hospitals in the Northern Nevada DSA.

22 233. NDN knew or should have known of the existence of DNW's prospective  
23 relationships with the current and/or potential health care providers in DNW's Northern Nevada  
24 DSA.

25 234. Upon information and belief, NDN has or is pursuing agreements and relationships  
with other hospitals in DNW's Northern Nevada DSA.

235. Upon information and belief, Defendant NDN committed intentionally wrongful  
acts intended or designed to disrupt DNW's agreements with those hospitals, including but not  
limited to:



- 1 i. Contacting hospitals and medical providers in the Northern Nevada  
2 DSA suggesting it would be to their advantage to apply for CMS  
3 OPO waivers to work with NDN, in connection with the supposedly  
4 impending commencement of the NTI in Reno, NV;
- 5 ii. Wrongly advising a Northern Nevada DSA hospital that its  
6 continued work with Plaintiff DNW violated Medicare regulations;
- 7 iii. Falsely announcing before community members and stakeholders  
8 that NDN's NTI transplant program requires NDN be the sole OPO  
9 serving Nevada hospitals, and that the NTI's transplant program will  
10 increase the number of Nevada citizens receiving organ transplants;
- 11 iv. Falsely representing to an international organ donor conference that  
12 NDN is the sole Nevada OPO;
- 13 v. Wrongly soliciting job applicants for positions at Northern Nevada  
14 DSA hospitals despite those hospitals not having a CMS OPO  
15 waiver to work with NDN in the Northern Nevada DSA; and
- 16 vi. Approaching DNW employees about applying for NDN jobs  
17 serving Northern Nevada DSA hospitals despite those hospitals not  
18 having a CMS OPO waiver to work with NDN in the Northern  
19 Nevada DSA.

20 236. NDN had no justification to commit these intentionally wrongful acts.

21 237. NDN intended to harm DNW by preventing DNW's current and prospective  
22 contractual relations with current and/or potential hospitals/health care providers with respect to  
23 DNW's OPO services in the Northern Nevada DSA.

24 238. Indeed, due to NDN's wrongful interference, NDN caused Renown Health to  
25 terminate unilaterally its longstanding Affiliation Agreement with DNW.

26 239. More so, due to NDN's wrongful interference and Renown Health terminating the  
27 Affiliation Agreement, DNW will be forced to consequently violate its Agreement with CMS  
28 concerning its position as the sole Northern Nevada OPO.

29 240. Upon information and belief, NDN's interference with DNW's current and  
30 prospective contractual relations was and is intentional, willful, malicious, without justification  
31 or excuse, and was perpetrated in an effort to obtain an unfair advantage over DNW in the  
32 Northern Nevada DSA.

1 241. DNW has suffered and will continue to suffer damages, including but not limited  
2 to compensatory and consequential damages as a direct and proximate result of NDN's intentional  
3 interference with DNW's current and/or prospective contractual relations, in an amount to be  
4 proven at trial.

5 **PRAYER FOR RELIEF**

6 **WHEREFORE**, Plaintiff Donor Network West, seeks a jury trial on all matters subject  
7 to trial by jury and respectfully requests that this Court issue the following relief:

- 8 1. For equitable and injunctive relief declaring:
  - 9 a. That by unilaterally terminating the Affiliation Agreement without  
10 cause and without having another organ donation services  
11 agreement in place with a qualified OPO certified in the Northern  
12 Nevada DSA, Defendant Renown Health violated the National  
13 Organ Transplant Act of 1984, the Social Security Act, and  
14 accompanying federal regulations, *see* 42 U.S.C. § 273(b)(3)(A);  
15 *see also* 42 U.S.C. § 1320b-8(a)(1)(C); 42 CFR § 482.45;
  - 16 b. Defendant Renown Health therefore wrongfully terminated the  
17 Affiliation Agreement;
  - 18 c. Defendant Renown Health's wrongful Affiliation Agreement  
19 termination is void and it is enjoined from any further unlawful  
20 Affiliation Agreement terminations;
  - 21 d. Renown Health wrongfully terminated the Affiliation Agreement by  
22 failing to comply with Affiliation Agreement – Section 10  
23 (Termination); and
  - 24 e. Defendant Renown Health is required to engage Plaintiff DNW  
25 consistent with the Affiliation Agreement's terms, until and unless

1 CMS issues a waiver pursuant to a determination on Renown  
2 Health's OPO waiver application.

3 2. Award compensatory, consequential, exemplary and punitive damages to Plaintiff  
4 DNW in an amount in excess of \$75,000.00 and to be determined at trial.

5 3. Award attorneys' fees and costs to Plaintiff DNW.

6 4. Grant to Plaintiff DNW whatever other relief is just and proper.

7 **DEMAND FOR JURY TRIAL**

8 Pursuant to Fed. R. Civ. P. 38, Plaintiff DNW demands a trial by jury on all issues so  
9 triable.

10 DATED this 8<sup>th</sup> day of December 2023.

11 HUTCHISON & STEFFEN, PLLC

12  
13 /s/ Jason D. Guinasso  
14 Jason D. Guinasso (Nevada Bar No. 8478)  
15 Devon T. Reese (Nevada Bar No. 7496)  
16 Alex Velto (Nevada Bar No. 14961)  
17 5371 Kietzke Lane  
18 Reno, Nevada 89511  
19 Telephone: (775) 853-8746  
20 Facsimile: (775) 201-9611  
21 [dreese@hutchlegal.com](mailto:dreese@hutchlegal.com)  
22 [avelto@hutchlegal.com](mailto:avelto@hutchlegal.com)  
23 [jguinasso@hutchlegal.com](mailto:jguinasso@hutchlegal.com)

19 DILWORTH PAXSON LLP  
20 Nina Spizer (*Pro Hac Vice Forthcoming*)  
21 Silvio Trentalange (*Pro Hac Vice Forthcoming*)  
22 1500 Market Street, Ste. 3500E  
23 Philadelphia, PA 19102  
24 Telephone: (215) 575-7000  
25 Facsimile: (215) 575-7200  
[nspizer@dilworthlaw.com](mailto:nspizer@dilworthlaw.com)  
[strentalange@dilworthlaw.com](mailto:strentalange@dilworthlaw.com)

*Attorneys for Plaintiff Donor Network West*

**CIVIL COMPLAINT VERIFICATION**

I, Janice Whaley, declare as follows:

1. I am the Chief Executive Officer for Donor Network West, the Plaintiff in the present case, and I am authorized to verify this Complaint on its behalf.
2. I have personal knowledge of the allegations set out in the foregoing Verified Complaint and if called on to testify I would competently testify as to the matters stated therein.
3. I verify under penalty of perjury under the laws of the United States of America that the factual statements in this Verified Complaint are true and correct to the best of my knowledge. 28 U.S.C. § 1746.

DATED this 7<sup>th</sup> day of December 2023.

  
\_\_\_\_\_  
JANICE WHALEY, CEO Donor Network West

**EXHIBITS INDEX**

<b>Index No.</b>	<b>Document Title</b>	<b>No. of Pages*</b>
<b>Exhibit 1</b>	CMS Agreement	2
<b>Exhibit 2</b>	Affiliation Agreement	8
<b>Exhibit 3</b>	Renown Health CMS OPO Waiver Application dated September 11, 2003	4
<b>Exhibit 4</b>	Renown Health Termination Letter dated September 29, 2023	2
<b>Exhibit 5</b>	Renown Health Termination Letter dated October 23, 2023	17
<b>Exhibit 6</b>	Donor Network West Response Letter to Renown Health dated October 19, 2023	5

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# EXHIBIT 1

CMS AGREEMENT

HUTCHISON & STEFFEN  
A PROFESSIONAL LLC

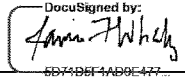
**HEALTH INSURANCE BENEFITS AGREEMENT****AGREEMENT WITH ORGAN PROCUREMENT ORGANIZATION PURSUANT TO §1138(b) OF THE SOCIAL SECURITY ACT (the Act)**

For the purpose of establishing eligibility under titles XVIII and XIX of the Act, Donor Network West  
hereinafter referred to as the Organ Procurement Organization, hereby agrees; *(Insert Name of Facility)*

- (A) To maintain compliance with the requirements of titles XVIII and XIX of the Act, §1138 of the Act, applicable regulations including the conditions set forth in Part 486, subpart G, title 42 of the Code of Federal Regulations, those conditions of the Organ Procurement and Transplantation Network established under §372 of the Public Health Service Act that have been approved by the Secretary, and to report promptly to the Centers for Medicare & Medicaid Services (CMS) any failure to do so;
- (B) To file a cost report in accordance with 42 CFR 413.24(f) within 5 months after the end of each fiscal year;
- (C) To permit CMS to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPO and to make a determination of reasonable cost based upon the cost report filed by the OPOs;
- (D) To provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;
- (E) To pay to CMS amounts that have been paid by CMS to transplant hospitals and that are determined to be in excess of the reasonable cost of the services provided by the OPO;
- (F) Not to charge any individual for items or services for which that individual is entitled to have payment made under §1881 of the Act;

This agreement, upon submission by the Organ Procurement Organization and upon acceptance for filing by the Secretary of Health and Human Services, shall be binding on the Organ Procurement Organization and the Secretary. The agreement may be terminated by either party in accordance with regulatory requirements. In the event of de-certification, costs for the procurement of organs will not be available to the Organ Procurement Organization furnished on or after the effective date of the de-certification.

This agreement shall become effective on the date specified below by the Secretary or his Delegate, and shall remain in effect as specified by 42 CFR 486.309 unless the OPO is de-certified.

<b>FOR THE ORGAN PROCUREMENT ORGANIZATION</b>	<b>ACCEPTED FOR SECRETARY OF HEALTH AND HUMAN SERVICES BY:</b>
NAME Janice F. Whaley 	NAME <i>R. Angelones</i>
TITLE CEO	TITLE Senior Health Insurance Specialist
DATE 5/5/2022   12:10 PM PDT	DATE 05/09/2022
EFFECTIVE DATE OF AGREEMENT 2/11/2022	

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0512. The time required to complete this information collection is estimated to average 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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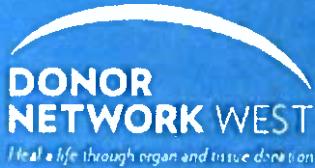
## **EXHIBIT 2**

AFFILIATION AGREEMENT

**HUTCHISON & STEFFEN**

A PROFESSIONAL LLC





**Main Office**  
12667 Alcosta Blvd., Ste. 500  
San Ramon, CA 94583

**Fresno Office**  
6721 H. Willow Ave., Ste. 104  
Fresno, CA 93710

**Nevada Office**  
1495 Ridgeview Dr., Ste. 90  
Reno, NV 89519

**Clinical Center**  
4550 Norris Canyon Rd., Ste. 100  
San Ramon, CA 94583

**Main Line**  
888.570.9400

**Donor Referral Hotline**  
1.800.55DONOR

Tax ID 94-3062436



## AFFILIATION AGREEMENT

**THIS AGREEMENT** is made by and between **Donor Network West**, a federally designated not-for-profit Organ Procurement Organization (OPO) and tissue and eye recovery agency, and **Renown Health**, a licensed general acute care hospital, hereafter "Hospital".

**WHEREAS**, the National Organ and Transplant Act (42 U.S.C. 273, et. seq.) ("Act") provides that organ procurement organizations shall establish effective agreements with hospitals and other healthcare entities in its service area to identify potential donors and to work in conjunction with donor institutions to establish a reliable system of acquiring, preserving and transporting donated organs and tissues; and

**WHEREAS**, Donor Network West is designated by the Secretary of Health and Human Services as the organ procurement agency to serve the counties of Northwestern Nevada (the "Donation Service Area"), in accordance with NRS Chapter 451.500 *et seq.* or successor statutes, henceforth referred to as the Uniform Anatomical Gift Act ("UAGA"), and federal law and regulations, including 42 CFR §482.45 *et seq.*, henceforth, also referred to as the "Medicare Conditions of Participation".

**WHEREAS**, Hospital is located in Donor Network West's Donation Service Area and is required by state and federal law and regulations, including the Medicare Conditions of Participation, to participate in Donor Network West's organ procurement program in accordance with the UAGA; and

**WHEREAS**, the parties are mutually dedicated to the increased availability of organs, tissue, and eyes for transplantation and research.

**NOW, THEREFORE**, the parties agree as follows:

### 1. Hospital Responsibilities

**Identification of Donors:** Hospital shall notify Donor Network West of all potential organ, tissue, and eye donors, and in conjunction therewith, further agrees to:

a. Promptly refer all deaths and imminent deaths for organ, tissue, and eye donation. Imminent deaths are defined in the clinical cues as ventilated patients with a non-survivable illness or injury. Notification of deaths shall be deemed "timely" if received within one hour of death. Notification of imminent deaths shall be deemed "timely" if received at the first indication that the patient has suffered a non-recoverable illness/injury or prior to plans for family discussions regarding comfort care or withdrawal of life-sustaining measures or prior to formal brain death declarations. Donor Network West shall respond to referrals in a timely manner as defined in Donor Network West Policy SE-P-004. Clinical triggers for referral shall be mutually agreed upon, and documented in Hospital policy, pursuant to 42 CFR 482.45 and in 42 CFR 486, subpart G.

b. Ensure timely and legal documentation of death, signed by hospital authorized personnel including a timely confirmation of the initial declaration in cases of death by neurologic criteria. Ensure documentation of death declarations in patient's medical record with date, time and signature of physicians. No physician involved in the documentation of death shall participate in any procedure relating to removal or transplantation of organs;

c. Medically manage the patient in order to maintain and maximize the option of organ donation for patients/families prior to the time Donor Network West takes over such maintenance, and enter appropriate documentation in the patient's medical record of all such donor management activities;

d. Provide access to and copies of the potential donor's medical record in accordance with federal and state law and Sections 5 and 6 below;

e. Assist Donor Network West in donor management during the pre-recovery process. Provide one-to-one nursing, under Donor Network West's protocols, and maintain potential donors while the testing and placement of organs / anatomical gift(s) takes place, as medically appropriate;

f. Work with Donor Network West to create a collaborative team approach to ensure all families of potential donors within Hospital are sensitively informed about the gift of organs, tissue, or eyes made by their family member's valid document of gift or registration as a donor, both as defined by the UAGA, or their option to donate organs, tissue, and eyes, whichever is applicable. In accordance with the requirements for designated requesters contained in 42 CFR 482.45, Donor Network West personnel shall bear primary responsibility as the designated/appropriate requestor for approaching the appropriate member of the defined classes who may authorize donation in accordance with NRS 451.566, collaborating with the Hospital staff and documenting consent or decline, as well as medical/social history. If requested by Hospital, Donor Network West will provide annual designated requestor training for qualified Hospital personnel;

g. Provide an appropriate location, including, as applicable, an operating room or other adequate facility for aseptic recovery of anatomical gifts, and personnel, as needed. Provide access to hospital services such as laboratory services, radiological services, cardiology services, anesthesia services, morgue access, and operating room availability on a 24/7 basis. Donor Network West may require urgent access to the operating room in cases when the potential organ donor becomes unstable or family requests impose time constraints;

h. Hospital hereby designates Donor Network West as its sole tissue and eye recovery agency and engages Donor Network West as Hospital's tissue and eye recovery agency pursuant to 42 CFR 482.45. Changes to this designation may be made only upon one-hundred eighty (180) days written notice to Donor Network West;

i. Work cooperatively with Donor Network West to facilitate continuing education to Hospital staff on all aspects of organ, tissue, and eye donation;

j. With the approval of both parties, designate a key committee to review and improve the donation process, including, but not limited to, the creation of policies and procedures with regard to the recognition of documents of gift as legally binding documents, pronouncement of brain death, and Donation after Circulatory Death (DCD).

k. Identify one or more staff members to serve as a donation liaison to Donor Network West;

l. Utilize discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

m. Honor the wishes of the decedent to donate organs, tissues, and eyes as expressed in a valid document of gift. Pursuant to the UAGA as defined in Nevada law (NRS 451.500), an anatomical gift, that is not revoked by the donor before death, is irrevocable and does not require the consent or concurrence of any person after the donor's death. This includes an anatomical gift that is made by means of and/or is registered in the Nevada Donor Registry. If the potential donor is found to be registered on the Nevada Donor Registry, Hospital will collaborate with Donor Network West to notify the donor's family members as appropriate, and address any questions or concerns they may have, but in no circumstances shall the hospital permit a third-party to effectively revoke a gift.

n. In case where there is no document of gift, ensure, in collaboration with Donor Network West, that the authorized donation decision-maker for each potential donor is informed of his/her options to donate organs, tissue, or eyes or to decline to donate.

o. In cooperation with Donor Network West, develop and implement a procedure to provide for the recovery of donated organs after circulatory death (DCD donation).

p. To ensure that the electronic simultaneous organ placement process prescribed by the United Network for Organ Sharing (UNOS) is utilized to maximize and expedite the anatomical gift, Hospital will provide Donor Network West with a wired/wireless secure Internet connection in or near the Critical Care units and Operating Room, in order for Donor Network West to upload donor information to UNOS and simultaneously share that information with prospective transplant centers;

## 2. OPO Responsibilities

Recovery of Organs/Tissues/Eyes: Donor Network West shall coordinate the retrieval of anatomical gift(s) and in conjunction therewith, further agrees to:

a. Promptly evaluate all potential donors to determine their medical suitability for organ, tissue, or eye donation on a 24/7 basis;

b. Review each potential donor patient's medical record to ensure documentation of brain death declarations with date, time, and signature of one (1) licensed physician, or, in the case of DCD donors, ensure appropriate documentation of cessation of heart and respiratory function, as defined by hospital policy;

c. During donation after brain death, Donor Network West will manage the donor during the pre-recovery process under Donor Network West's protocols and procedures. During DCD donation, the attending physician or designee shall continue to medically manage the patient until circulatory death occurs;

d. Work with Hospital on creating a collaborative team approach to ensure all families of potential donors within Hospital are sensitively informed about the potential donor's decision to donate as documented by valid document of gift, or the family's option to donate, as applicable. Donor Network West personnel shall bear primary responsibility for approaching the family and documenting authorization or refusal, as well as medical/social history;

e. Coordinate surgical procedures and personnel for the organ, tissue or eye recovery, including the coordination and provision of an appropriately licensed or otherwise qualified recovery team. In the case of tissue and eye recovery, Donor Network West will coordinate surgical recovery, utilizing trained recovery technicians;

f. If the potential donor is determined to be a coroner's case, Donor Network West will ensure that the coroner or medical examiner is notified of the death and all pertinent information pursuant to any existing protocol, and that any required approval for recovery is documented in the medical record;

g. Preserve, transport, and distribute organs for transplantation according to the guidelines established by the Organ Procurement and Transplantation Network, and otherwise facilitate the use of anatomical gift(s) as required by the UAGA;

h. Provide follow-up communication with the donor family;

i. Provide continuing education to Hospital staff on all aspects of donation, including DCD donation;

j. Utilize discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

k. Record promptly and maintain all information pertaining to Donor Network West's performance of duties and services under this Agreement and Donor Network West's records relating to services performed hereunder shall be available to Hospital upon request, subject to applicable laws and regulations.

3. Donor Network West Organ Surgical Recovery Team Responsibilities

a. Donor Network West shall, at the request of Hospital, provide Hospital with any professional licensing or credentialing information provided by the recovery teams, which information shall have been represented by such recovery teams and Donor Network West to be complete and accurate on the members participating in the recovery procedure. State licensure is not required for organ or tissue recovery.

b. Donor Network West shall utilize Hospital's staff physicians to the extent reasonably available, to assist Donor Network West in evaluating potential organ donors to determine their medical suitability for donation. However, when Hospital's physicians are not available, Hospital grants Donor Network West permission to consult with licensed and qualified medical professionals of its choice to assist in such evaluation.

4. Hospital Policies and Protocols: Hospital and Donor Network West shall cooperate in developing and approving policies and procedures to maximize donation and to further implement the provisions of this Agreement, 42 CFR 482.45 and applicable Joint Commission standards, and for compliance with all applicable laws, regulations, and standards relating to the donation of anatomical gift(s).

5. Death Record Review: In order to conduct necessary reviews of records in accordance with the 42 CFR 482.45 and 42 CFR 486 part G, Donor Network West shall have access to review all death records to improve identification of potential donors. This review enables both parties to evaluate and monitor the effectiveness of the services provided and to provide a means to verify compliance with all applicable laws, regulations, and standards relating to the donation of anatomical gift(s). Donor Network West will provide Hospital with an analysis and evaluation of Hospital's organ and tissue donation process.

6. Electronic Health Records: In the event that Hospital implements an electronic health records system, Hospital will provide Donor Network West timely access to the patient records within that system to facilitate all aspects of donation and death record reviews.

7. Confidentiality: All patient information is considered confidential and each party shall maintain in strict confidence, consistent with applicable federal and state law, any information disclosed by Hospital to Donor Network West or an agent of Donor Network West. Hospital acknowledges that HIPAA, at 45 CFR 164.512(h), allows information to be released to OPOs or other entities involved in organ and tissue donation and transplantation without patient release. OPOs are not Business Associates of Hospitals, and do not enter into Business Associate Agreements. In addition, disclosure may occur under the following circumstances:

a. Where disclosure is required under any federal or state law or regulation;

b. Where such information is used for the compilation of statistical data upon request of other organizations. However, in no event shall the parties disclose the name, home address, social security number, names of next-of-kin of a patient, or other patient identifying information for this purpose;

c. For Donor Network West or IRB approved research projects, if and only if all patient identifiers have been removed, or if the information is subject to a Limited Data Use Agreement between Hospital and researcher, if applicable.

8. Hospital Reimbursement: Hospital agrees to provide Donor Network West with an itemized bill (request for reimbursement) for directed services incurred for all patients accepted by Donor Network West as donors within seven months of the close of the case. Failure to provide Donor Network West with a request for reimbursement within this time frame will result in the elimination of any liability on the part of Donor Network West for hospital services provided. Donor Network West agrees to pay Hospital with respect to donor evaluation, donor maintenance, and recovery of anatomical gift(s), pursuant to the Donor Hospital Case Rate Reimbursement

Schedule in effect for the date of recovery. The Schedule is attached hereto as Exhibit A, and incorporated herein Schedule will be reviewed annually and updated periodically.

9. **Emergency Preparedness:** In accordance with Centers for Medicare and Medicaid Services (CMS) 42 CFR §§486.360, Donor Network West shall maintain an emergency preparedness plan that strives to ensure continuation of operations during emergency situations. In the event of a natural, technological or man-made disaster, Donor Network West will provide notification to the donor hospital when emergency situations impact normal processes. Donor Network West will fulfill responsibilities outlined in the affiliation agreement to the best of its ability. Hospital shall maintain an emergency preparedness plan. In the event of a natural, technological or man-made disaster, Hospital will notify Donor Network West when emergency situations impact normal processes or Hospital function, notify Donor Network West when emergency situations threaten the safety and well-being of Donor Network West staff, and fulfill responsibilities outlined in the affiliation agreement to the best of its ability.

10. **Termination:** This Agreement may be terminated by either party only upon the occurrence of one or more of the following circumstances:

- a. Decertification by the CMS of Donor Network West as the designated organ procurement organization for Hospital;
- b. Upon designation of another organ procurement organization by the CMS to be Hospital's designated organ procurement organization;
- c. Upon the granting of a waiver to Hospital by the CMS to work with another organ procurement organization; or
- d. Upon a showing by Hospital that it is no longer subject to compliance with any federal or state regulation requiring that it refer potential organ and tissue donors to any organ procurement organization.

This agreement shall stand as a document without expiration. Either party desiring to terminate this Agreement in response to any of the aforesaid circumstances or without cause shall provide as reasonable notice as is possible, but in no case less than ninety (90) days' written notice to the other party. Such notice shall specifically state the reason for termination of the Agreement, and such party desiring to terminate this Agreement shall provide such documentation to the other party supporting the reason so stated.

## 12. **Insurance**

a. **General and Professional Liability Insurance:** Each party will obtain and maintain comprehensive general liability insurance (including coverage for professional liability) in connection with its obligations under this Agreement. Such insurance coverage shall be in amounts not less than \$1 million per claim/\$3 million annual aggregate, and coverage shall be insured through an insurer that is qualified to do business in the State of Nevada. Each party shall bear its cost of such insurance, and certificates of insurance evidencing such coverage shall be made available to the parties upon their request. Any insurance required under this section may be obtained through a program(s) of self-insurance.

b. **Workers' Compensation:** Donor Network West is providing workers' compensation coverage pursuant to the State of Nevada for its employees and contractors providing services under this agreement and can provide evidence of coverage as requested.

13. **Professional and Administrative Responsibility:** The parties agree that Hospital retains professional and administrative responsibility for all services rendered by Donor Network West, to the extent permitted by federal law.

14. **Compliance:** Donor Network West and Hospital agree to comply with all federal, state, and local laws and regulations, which pertain to the performance of this Agreement, including, without limitation, applicable regulations promulgated by OSHA, CMS, OPTN, CDC, and FDA, as applicable. Hospital has no legal obligation to vaccinate Donor Network West staff. Furthermore, Donor Network West staff are not hospital employees and are not required to attend hospital orientation or other programs mandated for staff. Donor Network West is solely responsible for maintaining records for Donor Network West employees with regard to job competencies, training, immunizations, and medical testing. Donor Network West agrees to work cooperatively with Hospital with regard to facilitating Hospital's demonstrated compliance with those standards of care and quality promulgated by the Joint Commission, which applies to the performance of this Agreement. Both parties agree to work cooperatively to implement appropriate changes, correct deficiencies, and/or establish policies required and/or recommended by the inspecting agencies.

15. **Notices:** All notices hereunder shall be in writing, delivered personally, by certified or registered mail, return receipt requested, or by overnight courier, and shall be deemed to have been duly given when delivered personally or when deposited in the United States mail, postage prepaid, or deposited with the overnight courier addressed as follows or such other addresses as may later be designated by the party:

If to Hospital:  
Renown Health  
1155 Mill Street, Z-1  
Reno, NV 89502  
Attn: Contract Coordinator

If to Donor Network West:  
Donor Network West  
12667 Alcosta Blvd., Suite 500  
San Ramon, CA 94583  
Attn: Chief Executive Officer

16. **Amendments:** This Agreement may be amended or modified at any time in writing and signed by authorized representatives of both parties. The parties agree to amend this agreement to the extent amendment is required to comply with applicable federal and state laws and regulations and any changes thereto.

17. **Governing Law:** This Agreement shall be governed by and construed in accordance with the laws of the State of Nevada and applicable federal law.

18. **Severability:** The provisions of this Agreement are severable. If any one or more provisions of this Agreement are held invalid, the remaining provisions shall continue in full force and effect.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, by affixing their signature below, each of the parties has caused this Agreement to be executed on its behalf by its duly authorized representative, to be effective as of the last date written below.

**Donor Network West**

12667 Alcosta Blvd., Suite 500

San Ramon, CA 94583

By: Janice F. Whaley  
(Signature)

JANICE F. Whaley  
(Printed Name)

CEO  
(Title or Position)

Date: 8/30/19

**Renown Health**

1155 Mill Street, Z-1

Reno, NV 89502

By: Erik Olson  
(Signature)

ERIK OLSON  
(Printed name)

CEO  
(Title or Position)

Date: 8/30/19

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EXHIBIT PAGE ONLY

## EXHIBIT 3

RENOWN HEALTH CMS OPS WAIVER APPLICATION DATED  
SEPTEMBER 11, 2023

HUTCHISON & STEFFEN

A PROFESSIONAL LLC





Administration  
10315 Professional Circle  
Reno, NV 89521

P 775-982-4100

September 11, 2023

Director of the Division of Technical Payment Policy  
Chronic Care Policy Group  
Center for Medicare  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

To Whom it May Concern,

This letter shall serve to inform you that we have made the decision to sign an Agreement with the Nevada Donor Network, Inc. (NVLV) to become the Organ Procurement Organization (OPO) provider for organ, tissue and eye recovery services for Renown Regional Medical Center, Renown South Meadows Medical Center, and Renown South Meadows Medical Center dba Renown Rehabilitation Hospital (collectively, "Renown") effective January 1, 2024. This decision was driven by the desire of the organization to improve the services we provide to the community we serve. As such, Renown is formally requesting a "*waiver*" by copy of this notice as it relates to NVLV, a high-performing, Nevada-based OPO in good standing with the Centers for Medicare and Medicaid Services (CMS) which is outside of the CMS designated service area for Renown.

This request is submitted in accordance with 42 CFR §486.308 titled *Designation of one OPO for each service area*.

"...(e) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that –

- (1) The waiver is expected to increase organ donations; and
- (2) The waiver will ensure equitable treatment of patients listed for transplant within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement."

It is the position of Renown that the above stated conditions in the CMS regulations are met through Renown's Agreement with NVLV as follows: NVLV is a Tier 1 OPO per the CMS April 2023 Organ Procurement Organizations (OPO) Annual Public Aggregated Performance Report. Based on this independently reported data, we are confident NVLV will assist Renown to "*increase organ donations*" in the hospital system as a result of our Agreement. Renown is confident this will be the case given NVLV's longstanding and consistent performance status as an OPO leader since 2012. We also believe NVLV's effective presence as a CMS-designated OPO covering 14 of the 17 counties in the State of Nevada (representing 80% of the state's population) will be an additional factor contributing to the success of this new relationship. The infrastructure of NVLV and location of its offices in proximity to



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Administration  
10315 Professional Circle  
Reno, NV 89521

P 775-982-4100

Renown also allows for more cost-effective coverage and service to our hospital and community, which we believe will positively impact CMS from a fiscal perspective.

Based on independently published and publicly available data from the CMS April 2023 Organ Procurement Organizations (OPO) Annual Public Aggregated Performance Report, NVLV's performance achieves higher relative outcomes for donation rate and transplantation rate in comparison with our current OPO provider named Donor Network West (CADN) as seen in Table 1. This is also true when analyzing population-based data for the comparison between CADN and NVLV in Table 2.

Table 1

Performance Measure	NVLV	CADN
CMS Donation Rate	15.95	10.89
CMS Donation Rate Tier Status	1A*	2C*
Age Adjusted Transplantation Rate	51.07	37.85
Age Adjusted Transplantation Rate Tier Status	1A*	2B*

\*'Intra-tier' classifications assign a letter "A-E" along with the tier level noting an OPO's placement within the tier for the donation and transplantation rates.

Source: CMS 2023 OPO Annual Performance Data

Table 2

	Population	Transplants	Donors	Deaths	DPMP*	TPMP**
NVLV	2,822,349	858	200	26,600	71	304
CADN	13,650,942	2207	385	109,609	28	161

\*Donors Per Million of Population served

\*\*Transplants Per Million of Population served

Source: OPTN/UNOS and SRTR January 2023 report

In addition, based on the recently published and publicly available **CMS 2023 OPO Aggregate Performance Report**, which monitors performance of all OPOs from January 1, 2021, through December 31, 2021, NVLV is ranked 6<sup>th</sup> out of 56 OPOs for donation rate (CADN is ranked 33<sup>rd</sup> out of the 56) and NVLV is ranked 5<sup>th</sup> out of 56 OPOs for transplantation rate (while CADN is ranked 22<sup>nd</sup> out of 56).

In accordance with CMS regulations, our Agreement with NVLV "will [continue to] ensure equitable treatment of patients listed for transplant within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter



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*into an agreement*", as follows: The process of organ allocation is driven by the relevant policies set forth by the Organ Procurement and Transplantation Network (OPTN). Because NVLV follows all national allocation policies set forth by the OPTN, the organs recovered for transplantation at Renown will continue to be allocated by NVLV in accordance with regulation for patients "listed for transplant within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement." As a matter of fact, because we believe our donation rates will improve in partnership with NVLV, this will positively impact the equitable treatment of patients listed throughout the region by making more organs available to those who desperately wait, no matter which donation service area they might be listed in.

Based on the objective performance data exemplified by NVLV since its transformation in 2012 and the positive impact Renown expects its agreement with NVLV will have on patients listed for transplant, we appreciate your consideration of this formal notice of our agreement with NVLV and this waiver request.

Thank you for your consideration.

Very Truly Yours,

A handwritten signature in black ink, appearing to read "Brian Erling".

Brian Erling, MD, MBA  
President and CEO

CC:

David Wright, CMS Quality Safety & Oversight Group

Steven Chikering, CMS Associate Regional Administrator, Western Division of Survey and Certification

Edgardo Japitana CMS Nurse Consultant, U.S. Department of Health and Human Services

Richard Whitley, Director, Nevada Department of Health and Human Services



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## EXHIBIT 4

RENOWN HEALTH TERMINATION LETTER DATED SEPTEMBER 29, 2023

HUTCHISON & STEFFEN  
A PROFESSIONAL LLC



**Renown Regional Medical Center** P 775-982-4100  
1155 Mill Street, N-11 F 775-982-5933  
Reno, Nevada 89502

September 29, 2023

Janice Whaley  
CEO Donor Network West  
5440 Reno Corporate Dr.  
Reno, NV 89511

Re: Notice to Terminate without Cause Affiliation Agreement

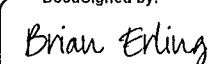
Dear Ms. Whaley:

Pursuant to Section 10 of Renown Health's and Donor Network West's Affiliation Agreement dated August 30, 2019, Renown Health provides this Notice of Termination. The reason for the termination is that Renown is partnering with a Nevada-based donor network. The termination will be effective 90 days from date of this letter.

Renown appreciates the many years of service that Donor Network West has provided to the donor community in Northern Nevada and the great work that both organizations have done on behalf of patients and families in critical need of organ donations.

Thank you for your partnership.

Very truly yours,

DocuSigned by:  
  
4C0C89FB2E7949B  
Brian Erling, M.D.  
CEO Renown Health



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EXHIBIT PAGE ONLY

## EXHIBIT 5

RENOWN HEALTH TERMINATION LETTER DATED OCTOBER 23, 2023

HUTCHISON & STEFFEN

A PROFESSIONAL LLC



**Renown Health**  
10315 Professional Circle  
Reno, NV 89521

Via: certified mail

Donor Network West  
Attn: Janice Whaley  
12667 Alcosta Blvd., Ste. 500  
San Ramon, CA 94583

Re: October 6, 2023 Notice of Termination of 2019 Affiliation Agreement

Dear Ms. Whaley-

Your letter dated October 19, 2023 to Dr. Brian Erling was forwarded to me for response.

Renown Health is certainly willing to discuss the concerns you raise in your letter. However, Renown Health disagrees that its Notice of Termination dated October 6, 2023 of the parties' August 30, 2019 Affiliation Agreement ("Agreement"), is invalid. Under Donor Network West's reading of the Agreement, it would be a contract of infinite duration, which is strongly disfavored under Nevada and federal law. See, e.g., *In re Draft Bars LLC*, No. 16-16656-MKN, 2020 WL 5806499, at \*8 (Bankr. D. Nev. Sept. 29, 2020) ("As a matter of law, contracts of perpetual duration are terminable at will.") (citing Restatement (Second) of Contracts § 33, cmt.d (1981)). Donor Network West appears to take the position that Renown Health was perpetually bound by the Agreement unless an external party, CMS, took action that would result in the termination of the Agreement. This interpretation would be contrary to public policy and void if true, but it is not supportable under the plain language of the Agreement.

Paragraph 10, Termination, provides that "[e]ither party desiring to terminate this Agreement" may do so "without cause", subject to at least a 90 day notice provision. Donor Network West's interpretation would render the "without cause" language of Paragraph 10 completely meaningless and would read this phrase out of the Agreement. See *Musser v. Bank of America*, 114 Nev. 945, 949, 964 P.2d 51, 54 (1998) ("A basic rule of contract interpretation is that '[e]very word must be given effect if at all possible.'") (quoting *Royal Indem. Co. v. Special Serv.*, 82 Nev. 148, 150, 413 P.2d 500, 502 (1966)). Donor Network West's argument that the "without cause" language could only be used "upon CMS review and approval" is grammatically impossible as the sentence states that termination may occur "in response to any of the aforesaid circumstances or without cause." (Agreement ¶ 10) (emphasis added).

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October 23, 2023  
Page 2

If this was not enough, Donor Network West appears to have forgotten that the specific “without cause” language was requested by Renown Health and agreed to by Donor Network West. For confirmation, please review the attached email chain and redlined draft by Donor Network West’s Kevin Campbell. Any attempt by Donor Network West to litigate and challenge Renown Health’s termination would be frivolous given the plain language of the Agreement as well as the unequivocal communication between the parties where “without cause” was added by Donor Network West to the Agreement.

That Donor Network West’s disagrees with our explanation is of no moment. The Agreement indisputably provides Renown the opportunity to terminate without cause consistent with Nevada law. Although unnecessary, Renown here responds to two of your arguments against recognizing the termination notice. One, you indicate that Donor Network West is a Nevada-based organization. The Agreement, on the first page, identifies Donor Network West’s headquarters as San Ramon, California. Notice under the Agreement was required to be sent to the corporate headquarters in San Ramon, California, per the Notice provision. That you have an office in Nevada does not negate Renown’s desire to affiliate with a Nevada-based organization.

Two, you also indicate that federal law mandates that Renown use only Donor Network West. Be advised that on September 11, 2023, Renown sought a waiver under 42 CFR § 486.308 from the Centers for Medicare and Medicaid services. See attached. Renown anticipates that that waiver will be granted in due course prior to the end of the 90 day termination window. Paragraph 10(c) of the Agreement specifically also permits termination in that instance, which would render any dispute by Donor Network West moot.

Renown Health is willing to discuss Donor Network West’s concerns throughout the notice period and commits to providing the full 90-day notice period, regardless of whether such is required, and will not terminate the Agreement prior to January 4, 2024. Should Donor Network West wish to negotiate a longer transition period, we are also willing to discuss extending that timeframe. Finally, we are not aware of any public disclosure of the Notice of Termination and any such awareness of the Notice would be the result of Donor Network West’s communications rather than of Renown Health’s.

Very truly yours,

/s/ Paul Harris

Paul Harris, Esq.

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## Mary Ann Ellis

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**From:** Jamie Winter  
**Sent:** Tuesday, September 3, 2019 10:40 AM  
**To:** Erik Olson  
**Cc:** Maricarmen Cresci  
**Subject:** RE: Contract review - Affiliation Agreement - Donor Network West  
**Attachments:** Renown - 8-30-19 - Redlined\_Addtl Renown Redlines.docx

Good morning-

Thank you for sending this along for my review. I am pleased with the revisions to which they agreed. I included one comment to you in the attached, revised version (see Section 15 "Notices") and included reference to the requirement that copies of notices must also be sent to Legal. After you confirm/revise the notice provision, as deemed necessary, I think you can move forward with execution.

Jamie

---

**From:** Erik Olson  
**Sent:** Friday, August 30, 2019 1:37 PM  
**To:** Jamie Winter <JWinter@renown.org>  
**Subject:** FW: Contract review - Affiliation Agreement - Donor Network West

fyi

---

**From:** Kevin Campbell [<mailto:KCampbell@dnwest.org>]  
**Sent:** Friday, August 30, 2019 11:54 AM  
**To:** Janice Whaley <[JWhaley@dnwest.org](mailto:JWhaley@dnwest.org)>; Erik Olson <[EOlson@renown.org](mailto:EOlson@renown.org)>  
**Cc:** Emily Lara <[ELara@dnwest.org](mailto:ELara@dnwest.org)>  
**Subject:** RE: Contract review - Affiliation Agreement - Donor Network West

**EXTERNAL EMAIL:** This email originated outside of Renown Health.  
**DO NOT CLICK** on links or attachments unless you recognize the sender and know the content is safe.  
**REPORT IT** to the Service Desk at 4042 and send it as an attachment to [infoprot@renown.org](mailto:infoprot@renown.org).

Hi Eric,

Please see below for responses in red. I have tracked the changes so you can easily review. As soon as Janice arrives in the office we will send you a signed version to fully execute.

Begin forwarded message:

**From:** Erik Olson <[EOlson@renown.org](mailto:EOlson@renown.org)>  
**Date:** August 30, 2019 at 11:01:13 AM PDT  
**To:** 'Janice Whaley' <[JWhaley@dnwest.org](mailto:JWhaley@dnwest.org)>  
**Cc:** Maricarmen Cresci <[MCresci@renown.org](mailto:MCresci@renown.org)>  
**Subject:** FW: Contract review - Affiliation Agreement - Donor Network West

Hi Janice,

I'm now having time to review the Affiliation Agreement. A couple of question/requests:

1. We will need to remove the indemnification language per direction of Renown Legal. If you feel language should remain, we will need our attorneys to discuss and draft. **We are removing the indemnification clause. Keep in mind that it was mutual so your legal would have probably been comfortable with the verbiage. In the interest of time, we will omit it.**
2. Please add termination for cause language under the Termination section. I'm comfortable with 90 day notice. This would likely only apply to the tissue and eye services, as CMS designates OPO. **Added.**
3. Hospital reimbursement section references a Schedule A. I'll need to track that down, unless you have it. **I have attached the hospital rates. I have also updated the contract to state that these are reviewed annually but updated periodically. We do not necessarily change them each year.**
4. Should I assume the lease agreement, which is separate, addresses the costs/reimbursement of the space you are using in the hospital? **Yes, we will encompass that aspect in the lease.**

Thank you,  
Erik

775-830-5691 – call my cell if you want to discuss.

---

**From:** Jamie Winter

**Sent:** Thursday, August 8, 2019 12:10 PM

**To:** Erik Olson <[EOlson@renown.org](mailto:EOlson@renown.org)>

**Cc:** Maricarmen Cresci <[MCresci@renown.org](mailto:MCresci@renown.org)>

**Subject:** FW: Contract review - Affiliation Agreement - Donor Network West

Hi Erik-

Unfortunately I can't redline or comment on the agreement within the body of the document as it is in PDF and already signed by the other party's representative.

**Legal Terms:** There are no glaring issues with the legal terms of the agreement with the exception of indemnification which I would prefer we strike as we usually don't agree to indemnify a business partner in the broad way that the document contemplates.

**Business/Operational Terms:** I also wanted to comment on the following:

1. Please confirm that Renown Health is the appropriate contracting entity and not RRMCM as the document references "Hospital".
2. Please confirm that you, as the business owner, have closely reviewed all the operational terms and obligations and we can achieve the obligations and meet the requirements of the document. Specifically please closely review:
  - a. Section 1
  - b. Section 4
  - c. Section 5
3. Please confirm that you are o.k. with no option to terminate the arrangement except in "for-cause" situations. There is no "Not for Cause" option which I would prefer was included.

Please let me know how you wish to handle. If you'd like to request a Word version I can mark-up the document and we can send it back for their review. I'm happy to help in whatever way needed.

Finally, attached hereto is a completed legal contract review form for your records.

Thanks!

Jamie Winter

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**From:** LegalReview

**Sent:** Thursday, August 08, 2019 10:23 AM

**To:** Jamie Winter <[JWinter@renown.org](mailto:JWinter@renown.org)>

**Subject:** FW: Contract review - Affiliation Agreement - Donor Network West

Hi Jamie,

Here is the Donor Network contract that we talked about where Erik wants your review with no specific questions. Please note that Erik is meeting with Donor Network on the 21<sup>st</sup> and would like your response prior.

<G:\Legal Department\Contracts\3-Vendors\Donor Network West>

Bekah

**Rebekah Riley, CP**

Paralegal

50 West Liberty Street, Suite 1100, N14

Reno, Nevada 89501

P: 775-982-4823

[rriley@renown.org](mailto:rriley@renown.org)

[For what matters most. A Report to Thank our Community](#)

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Confidentiality Note: This e-mail message contains information from the Donor Network West that may be privileged and/or confidential. If you are not the addressee or an authorized recipient of this message, any distribution, copying, publication, or use of this information for any purpose is prohibited. Please notify the sender immediately by e-mail and then delete this message.



### AFFILIATION AGREEMENT

**THIS AGREEMENT** is made by and between **Donor Network West**, a federally designated not-for-profit Organ Procurement Organization (OPO) and tissue and eye recovery agency, and **Renown Health**, a licensed general acute care hospital, hereafter "Hospital".

**WHEREAS**, the National Organ and Transplant Act (42 U.S.C. 273, et. seq.) ("Act") provides that organ procurement organizations shall establish effective agreements with hospitals and other healthcare entities in its service area to identify potential donors and to work in conjunction with donor institutions to establish a reliable system of acquiring, preserving and transporting donated organs and tissues; and

**WHEREAS**, Donor Network West is designated by the Secretary of Health and Human Services as the organ procurement agency to serve the counties of Northwestern Nevada (the "Donation Service Area"), in accordance with NRS Chapter 451.500 *et seq.* or successor statutes, henceforth referred to as the Uniform Anatomical Gift Act ("UAGA"), and federal law and regulations, including 42 CFR §482.45 *et seq.*, henceforth, also referred to as the "Medicare Conditions of Participation".

**WHEREAS**, Hospital is located in Donor Network West's Donation Service Area and is required by state and federal law and regulations, including the Medicare Conditions of Participation, to participate in Donor Network West's organ procurement program in accordance with the UAGA; and

**WHEREAS**, the parties are mutually dedicated to the increased availability of organs, tissue, and eyes for transplantation and research.

**NOW, THEREFORE**, the parties agree as follows:

1. Hospital Responsibilities

**Identification of Donors:** Hospital shall notify Donor Network West of all potential organ, tissue, and eye donors, and in conjunction therewith, further agrees to:

a. Promptly refer all deaths and imminent deaths for organ, tissue, and eye donation. Imminent deaths are defined in the clinical cues as ventilated patients with a non-survivable illness or injury. Notification of deaths shall be deemed "timely" if received within one hour of death. Notification of imminent deaths shall be deemed "timely" if received at the first indication that the patient has suffered a non-recoverable illness/injury or prior to plans for family discussions regarding comfort care or withdrawal of life-sustaining measures or prior to formal brain death declarations. Donor Network West shall respond to referrals in a timely manner as defined in Donor Network West Policy SE-P-004. Clinical triggers for referral shall be mutually agreed upon, and documented in Hospital policy, pursuant to 42 CFR 482.45 and in 42 CFR 486, subpart G.

b. Ensure timely and legal documentation of death, signed by hospital authorized personnel including a timely confirmation of the initial declaration in cases of death by neurologic criteria. Ensure documentation of death declarations in patient's medical record with date, time and signature of physicians. No physician involved in the documentation of death shall participate in any procedure relating to removal or transplantation of organs;

c. Medically manage the patient in order to maintain and maximize the option of organ donation for patients/families prior to the time Donor Network West takes over such maintenance, and enter appropriate documentation in the patient's medical record of all such donor management activities;

d. Provide access to and copies of the potential donor's medical record in accordance with federal and state law and Sections 5 and 6 below;

Main Office  
12667 Alcosta Blvd., Ste. 500  
San Ramon, CA 94583

Fresno Office  
6721 N. Willow Ave., Ste. 104  
Fresno, CA 93710

Nevada Office  
1495 Ridgeview Dr., Ste. 90  
Reno, NV 89519

Clinical Center  
4550 Norris Canyon Rd., Ste. 100  
San Ramon, CA 94583

Main Line  
888.570.9400

Donor Referral Hotline  
1.800.55DONOR

Tax ID 94-3062436



e. Assist Donor Network West in donor management during the pre-recovery process. Provide one-to-one nursing, under Donor Network West's protocols, and maintain potential donors while the testing and placement of organs / anatomical gift(s) takes place, as medically appropriate;

f. Work with Donor Network West to create a collaborative team approach to ensure all families of potential donors within Hospital are sensitively informed about the gift of organs, tissue, or eyes made by their family member's valid document of gift or registration as a donor, both as defined by the UAGA, or their option to donate organs, tissue, and eyes, whichever is applicable. In accordance with the requirements for designated requesters contained in 42 CFR 482.45, Donor Network West personnel shall bear primary responsibility as the designated/appropriate requestor for approaching the appropriate member of the defined classes who may authorize donation in accordance with NRS 451.566, collaborating with the Hospital staff and documenting consent or decline, as well as medical/social history. If requested by Hospital, Donor Network West will provide annual designated requestor training for qualified Hospital personnel;

g. Provide an appropriate location, including, as applicable, an operating room or other adequate facility for aseptic recovery of anatomical gifts, and personnel, as needed. Provide access to hospital services such as laboratory services, radiological services, cardiology services, anesthesia services, morgue access, and operating room availability on a 24/7 basis. Donor Network West may require urgent access to the operating room in cases when the potential organ donor becomes unstable or family requests impose time constraints;

h. Hospital hereby designates Donor Network West as its sole tissue and eye recovery agency and engages Donor Network West as Hospital's tissue and eye recovery agency pursuant to 42 CFR 482.45. Changes to this designation may be made only upon one-hundred eighty (180) days written notice to Donor Network West;

i. Work cooperatively with Donor Network West to facilitate continuing education to Hospital staff on all aspects of organ, tissue, and eye donation;

j. With the approval of both parties, designate a key committee to review and improve the donation process, including, but not limited to, the creation of policies and procedures with regard to the recognition of documents of gift as legally binding documents, pronouncement of brain death, and Donation after Circulatory Death (DCD).

k. Identify one or more staff members to serve as a donation liaison to Donor Network West;

l. Utilize discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

m. Honor the wishes of the decedent to donate organs, tissues, and eyes as expressed in a valid document of gift. Pursuant to the UAGA as defined in Nevada law (NRS 451.500), an anatomical gift, that is not revoked by the donor before death, is irrevocable and does not require the consent or concurrence of any person after the donor's death. This includes an anatomical gift that is made by means of and/or is registered in the Nevada Donor Registry. If the potential donor is found to be registered on the Nevada Donor Registry, Hospital will collaborate with Donor Network West to notify the donor's family members as appropriate, and address any questions or concerns they may have, but in no circumstances shall the hospital permit a third-party to effectively revoke a gift.

n. In case where there is no document of gift, ensure, in collaboration with Donor Network West, that the authorized donation decision-maker for each potential donor is informed of his/her options to donate organs, tissue, or eyes or to decline to donate.

o. In cooperation with Donor Network West, develop and implement a procedure to provide for the recovery of donated organs after circulatory death (DCD donation).

p. To ensure that the electronic simultaneous organ placement process prescribed by the United Network for Organ Sharing (UNOS) is utilized to maximize and expedite the anatomical gift, Hospital will provide Donor Network West with a wired/wireless secure Internet connection in or near the Critical Care units and Operating Room, in order for Donor Network West to upload donor information to UNOS and simultaneously share that information with prospective transplant centers;

## 2. OPO Responsibilities

Recovery of Organs/Tissues/Eyes: Donor Network West shall coordinate the retrieval of anatomical gift(s) and in conjunction therewith, further agrees to:

a. Promptly evaluate all potential donors to determine their medical suitability for organ, tissue, or eye donation on a 24/7 basis;

b. Review each potential donor patient's medical record to ensure documentation of brain death declarations with date, time, and signature of one (1) licensed physician, or, in the case of DCD donors, ensure appropriate documentation of cessation of heart and respiratory function, as defined by hospital policy;

c. During donation after brain death, Donor Network West will manage the donor during the pre-recovery process under Donor Network West's protocols and procedures. During DCD donation, the attending physician or designee shall continue to medically manage the patient until circulatory death occurs;

d. Work with Hospital on creating a collaborative team approach to ensure all families of potential donors within Hospital are sensitively informed about the potential donor's decision to donate as documented by valid document of gift, or the family's option to donate, as applicable. Donor Network West personnel shall bear primary responsibility for approaching the family and documenting authorization or refusal, as well as medical/social history;

e. Coordinate surgical procedures and personnel for the organ, tissue or eye recovery, including the coordination and provision of an appropriately licensed or otherwise qualified recovery team. In the case of tissue and eye recovery, Donor Network West will coordinate surgical recovery, utilizing trained recovery technicians;

f. If the potential donor is determined to be a coroner's case, Donor Network West will ensure that the coroner or medical examiner is notified of the death and all pertinent information pursuant to any existing protocol, and that any required approval for recovery is documented in the medical record;

g. Preserve, transport, and distribute organs for transplantation according to the guidelines established by the Organ Procurement and Transplantation Network, and otherwise facilitate the use of anatomical gift(s) as required by the UAGA;

h. Provide follow-up communication with the donor family;

i. Provide continuing education to Hospital staff on all aspects of donation, including DCD donation;

j. Utilize discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

k. Record promptly and maintain all information pertaining to Donor Network West's performance of duties and services under this Agreement and Donor Network West's records relating to services performed hereunder shall be available to Hospital upon request, subject to applicable laws and regulations.

3. Donor Network West Organ Surgical Recovery Team Responsibilities

a. Donor Network West shall, at the request of Hospital, provide Hospital with any professional licensing or credentialing information provided by the recovery teams, which information shall have been represented by such recovery teams and Donor Network West to be complete and accurate on the members participating in the recovery procedure. State licensure is not required for organ or tissue recovery.

b. Donor Network West shall utilize Hospital's staff physicians to the extent reasonably available, to assist Donor Network West in evaluating potential organ donors to determine their medical suitability for donation. However, when Hospital's physicians are not available, Hospital grants Donor Network West permission to consult with licensed and qualified medical professionals of its choice to assist in such evaluation.

4. Hospital Policies and Protocols: Hospital and Donor Network West shall cooperate in developing and approving policies and procedures to maximize donation and to further implement the provisions of this Agreement, 42 CFR 482.45 and applicable Joint Commission standards, and for compliance with all applicable laws, regulations, and standards relating to the donation of anatomical gift(s).

5. Death Record Review: In order to conduct necessary reviews of records in accordance with the 42 CFR 482.45 and 42 CFR 486 part G, Donor Network West shall have access to review all death records to improve identification of potential donors. This review enables both parties to evaluate and monitor the effectiveness of the services provided and to provide a means to verify compliance with all applicable laws, regulations, and standards relating to the donation of anatomical gift(s). Donor Network West will provide Hospital with an analysis and evaluation of Hospital's organ and tissue donation process.

6. Electronic Health Records: In the event that Hospital implements an electronic health records system, Hospital will provide Donor Network West timely access to the patient records within that system to facilitate all aspects of donation and death record reviews.

7. Confidentiality: All patient information is considered confidential and each party shall maintain in strict confidence, consistent with applicable federal and state law, any information disclosed by Hospital to Donor Network West or an agent of Donor Network West. Hospital acknowledges that HIPAA, at 45 CFR 164.512(h), allows information to be released to OPOs or other entities involved in organ and tissue donation and transplantation without patient release. OPOs are not Business Associates of Hospitals, and do not enter into Business Associate Agreements. In addition, disclosure may occur under the following circumstances:

a. Where disclosure is required under any federal or state law or regulation;

b. Where such information is used for the compilation of statistical data upon request of other organizations. However, in no event shall the parties disclose the name, home address, social security number, names of next-of-kin of a patient, or other patient identifying information for this purpose;

c. For Donor Network West or IRB approved research projects, if and only if all patient identifiers have been removed, or if the information is subject to a Limited Data Use Agreement between Hospital and researcher, if applicable.

8. Hospital Reimbursement: Hospital agrees to provide Donor Network West with an itemized bill (request for reimbursement) for directed services incurred for all patients accepted by Donor Network West as donors within seven months of the close of the case. Failure to provide Donor Network West with a request for reimbursement within this time frame will result in the elimination of any liability on the part of Donor Network West for hospital services provided. Donor Network West agrees to pay Hospital with respect to donor evaluation, donor maintenance, and recovery of anatomical gift(s), pursuant to the Donor Hospital Case Rate Reimbursement

Schedule in effect for the date of recovery. The Schedule is attached hereto as Exhibit A, and incorporated herein Schedule will be ~~reviewed annually and~~ updated ~~periodically~~ annually.

9. Emergency Preparedness: In accordance with Centers for Medicare and Medicaid Services (CMS) 42 CFR §§486.360, Donor Network West shall maintain an emergency preparedness plan that strives to ensure continuation of operations during emergency situations. In the event of a natural, technological or man-made disaster, Donor Network West will provide notification to the donor hospital when emergency situations impact normal processes. Donor Network West will fulfill responsibilities outlined in the affiliation agreement to the best of its ability. Hospital shall maintain an emergency preparedness plan. In the event of a natural, technological or man-made disaster, Hospital will notify Donor Network West when emergency situations impact normal processes or Hospital function, notify Donor Network West when emergency situations threaten the safety and well-being of Donor Network West staff, and fulfill responsibilities outlined in the affiliation agreement to the best of its ability.

10. Termination: This Agreement may be terminated by either party only upon the occurrence of one or more of the following circumstances:

- a. Decertification by the CMS of Donor Network West as the designated organ procurement organization for Hospital;
- b. Upon designation of another organ procurement organization by the CMS to be Hospital's designated organ procurement organization;
- c. Upon the granting of a waiver to Hospital by the CMS to work with another organ procurement organization; or
- d. Upon a showing by Hospital that it is no longer subject to compliance with any federal or state regulation requiring that it refer potential organ and tissue donors to any organ procurement organization.

This agreement shall stand as a document without expiration. Either party desiring to terminate this Agreement in response to any of the aforesaid circumstances ~~or without cause~~ shall provide as reasonable notice as is possible, but in no case less than ~~ninetyone hundred eighty (90+80)~~ ninetyone hundred eighty (90+80) days' written notice to the other party. Such notice shall specifically state the reason for termination of the Agreement, and such party desiring to terminate this Agreement shall provide such documentation to the other party supporting the reason so stated.

~~11. Indemnification: Each Party shall defend, indemnify, and hold the other parties and their officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorneys' fees), or claims for injury or damages arising out of the performance of this Agreement, but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of the indemnifying party or its officers, employees, and agents.~~

12. Insurance

a. General and Professional Liability Insurance: Each party will obtain and maintain comprehensive general liability insurance (including coverage for professional liability) in connection with its obligations under this Agreement. Such insurance coverage shall be in amounts not less than \$1 million per claim/\$3 million annual aggregate, and coverage shall be insured through an insurer that is qualified to do business in the State of Nevada. Each party shall bear its cost of such insurance, and certificates of insurance evidencing such coverage shall be made available to the parties upon their request. Any insurance required under this section may be obtained through a program(s) of self-insurance.

b. Workers' Compensation: Donor Network West is providing workers' compensation coverage pursuant to the State of Nevada for its employees and contractors providing services under this agreement and can provide evidence of coverage as requested.



13. Professional and Administrative Responsibility: The parties agree that Hospital retains professional and administrative responsibility for all services rendered by Donor Network West, to the extent permitted by federal law.

14. Compliance: Donor Network West and Hospital agree to comply with all federal, state, and local laws and regulations, which pertain to the performance of this Agreement, including, without limitation, applicable regulations promulgated by OSHA, CMS, OPTN, CDC, and FDA, as applicable. Hospital has no legal obligation to vaccinate Donor Network West staff. Furthermore, Donor Network West staff are not hospital employees and are not required to attend hospital orientation or other programs mandated for staff. Donor Network West is solely responsible for maintaining records for Donor Network West employees with regard to job competencies, training, immunizations, and medical testing. Donor Network West agrees to work cooperatively with Hospital with regard to facilitating Hospital's demonstrated compliance with those standards of care and quality promulgated by the Joint Commission, which applies to the performance of this Agreement. Both parties agree to work cooperatively to implement appropriate changes, correct deficiencies, and/or establish policies required and/or recommended by the inspecting agencies.

15. Notices: All notices hereunder shall be in writing, delivered personally, by certified or registered mail, return receipt requested, or by overnight courier, and shall be deemed to have been duly given when delivered personally or when deposited in the United States mail, postage prepaid, or deposited with the overnight courier addressed as follows or such other addresses as may later be designated by the party:

If to Hospital:  
Renown Health  
1155 Mill Street, Z-1  
Reno, NV 89502  
Attn: Contract Coordinator

With a copy to:  
[Renown Health](#)  
[Legal Department](#)  
[50 West Liberty Street, Suite 1100](#)  
[Reno, Nevada 89501](#)

If to Donor Network West:  
Donor Network West  
12667 Alcosta Blvd., Suite 500  
San Ramon, CA 94583  
Attn: Chief Executive Officer

**Commented [JW1]:** Erik: Is this the correct address?  
Adding Legal as well.

16. Amendments: This Agreement may be amended or modified at any time in writing and signed by authorized representatives of both parties. The parties agree to amend this agreement to the extent amendment is required to comply with applicable federal and state laws and regulations and any changes thereto.

17. Governing Law: This Agreement shall be governed by and construed in accordance with the laws of the State of Nevada and applicable federal law.

18. Severability: The provisions of this Agreement are severable. If any one or more provisions of this Agreement are held invalid, the remaining provisions shall continue in full force and effect.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, by affixing their signature below, each of the parties has caused this Agreement to be executed on its behalf by its duly authorized representative, to be effective as of the last date written below.

**Donor Network West**  
12667 Alcosta Blvd., Suite 500  
San Ramon, CA 94583

By: \_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Title or Position)

Date: \_\_\_\_\_

**Renown Health**  
1155 Mill Street, Z-1  
Reno, NV 89502

By: \_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Printed name)

\_\_\_\_\_  
(Title or Position)

Date: \_\_\_\_\_



Administration  
10315 Professional Circle  
Reno, NV 89521

P 775-982-4100

September 11, 2023

Director of the Division of Technical Payment Policy  
Chronic Care Policy Group  
Center for Medicare  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

To Whom it May Concern,

This letter shall serve to inform you that we have made the decision to sign an Agreement with the Nevada Donor Network, Inc. (NVLV) to become the Organ Procurement Organization (OPO) provider for organ, tissue and eye recovery services for Renown Regional Medical Center, Renown South Meadows Medical Center, and Renown South Meadows Medical Center dba Renown Rehabilitation Hospital (collectively, "Renown") effective January 1, 2024. This decision was driven by the desire of the organization to improve the services we provide to the community we serve. As such, Renown is formally requesting a "**waiver**" by copy of this notice as it relates to NVLV, a high-performing, Nevada-based OPO in good standing with the Centers for Medicare and Medicaid Services (CMS) which is outside of the CMS designated service area for Renown.

This request is submitted in accordance with 42 CFR §486.308 titled ***Designation of one OPO for each service area.***

"...(e) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that –

- (1) The waiver is expected to increase organ donations; and
- (2) The waiver will ensure equitable treatment of patients listed for transplant within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement."

It is the position of Renown that the above stated conditions in the CMS regulations are met through Renown's Agreement with NVLV as follows: NVLV is a Tier 1 OPO per the CMS April 2023 Organ Procurement Organizations (OPO) Annual Public Aggregated Performance Report. Based on this independently reported data, we are confident NVLV will assist Renown to "**increase organ donations**" in the hospital system as a result of our Agreement. Renown is confident this will be the case given NVLV's longstanding and consistent performance status as an OPO leader since 2012. We also believe NVLV's effective presence as a CMS-designated OPO covering 14 of the 17 counties in the State of Nevada (representing 80% of the state's population) will be an additional factor contributing to the success of this new relationship. The infrastructure of NVLV and location of its offices in proximity to



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10315 Professional Circle  
Reno, NV 89521

P 775-982-4100

Renown also allows for more cost-effective coverage and service to our hospital and community, which we believe will positively impact CMS from a fiscal perspective.

Based on independently published and publicly available data from the CMS April 2023 Organ Procurement Organizations (OPO) Annual Public Aggregated Performance Report, NVLV's performance achieves higher relative outcomes for donation rate and transplantation rate in comparison with our current OPO provider named Donor Network West (CADN) as seen in Table 1. This is also true when analyzing population-based data for the comparison between CADN and NVLV in Table 2.

Table 1

Performance Measure	NVLV	CADN
CMS Donation Rate	15.95	10.89
CMS Donation Rate Tier Status	1A*	2C*
Age Adjusted Transplantation Rate	51.07	37.85
Age Adjusted Transplantation Rate Tier Status	1A*	2B*

\*'Intra-tier' classifications assign a letter "A-E" along with the tier level noting an OPO's placement within the tier for the donation and transplantation rates.

Source: CMS 2023 OPO Annual Performance Data

Table 2

	Population	Transplants	Donors	Deaths	DPMP*	TPMP**
NVLV	2,822,349	858	200	26,600	71	304
CADN	13,650,942	2207	385	109,609	28	161

\*Donors Per Million of Population served

\*\*Transplants Per Million of Population served

Source: OPTN/UNOS and SRTR January 2023 report

In addition, based on the recently published and publicly available **CMS 2023 OPO Aggregate Performance Report**, which monitors performance of all OPOs from January 1, 2021, through December 31, 2021, NVLV is ranked 6<sup>th</sup> out of 56 OPOs for donation rate (CADN is ranked 33<sup>rd</sup> out of the 56) and NVLV is ranked 5<sup>th</sup> out of 56 OPOs for transplantation rate (while CADN is ranked 22<sup>nd</sup> out of 56).

In accordance with CMS regulations, our Agreement with NVLV "will [continue to] ensure equitable treatment of patients listed for transplant within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter



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*into an agreement*", as follows: The process of organ allocation is driven by the relevant policies set forth by the Organ Procurement and Transplantation Network (OPTN). Because NVLV follows all national allocation policies set forth by the OPTN, the organs recovered for transplantation at Renown will continue to be allocated by NVLV in accordance with regulation for patients "listed for transplant within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement." As a matter of fact, because we believe our donation rates will improve in partnership with NVLV, this will positively impact the equitable treatment of patients listed throughout the region by making more organs available to those who desperately wait, no matter which donation service area they might be listed in.

Based on the objective performance data exemplified by NVLV since its transformation in 2012 and the positive impact Renown expects its agreement with NVLV will have on patients listed for transplant, we appreciate your consideration of this formal notice of our agreement with NVLV and this waiver request.

Thank you for your consideration.

Very Truly Yours,

A handwritten signature in black ink, appearing to read "Brian Erling", written over a light blue horizontal line.

Brian Erling, MD, MBA  
President and CEO

CC:

David Wright, CMS Quality Safety & Oversight Group

Steven Chikering, CMS Associate Regional Administrator, Western Division of Survey and Certification

Edgardo Japitana CMS Nurse Consultant, U.S. Department of Health and Human Services

Richard Whitley, Director, Nevada Department of Health and Human Services



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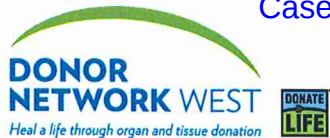
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EXHIBIT PAGE ONLY

## **EXHIBIT 6**

DNW RESPONSE LETTER TO RENOWN HEALTH DATED OCTOBER 19,  
2023

**HUTCHISON & STEFFEN**

A PROFESSIONAL LLC



October 19, 2023

Sent *via* certified mail and e-mail to:

Brian Erling, M.D.  
CEO Renown Health  
Renown Regional Medical Center  
1155 Mill Street N-11  
Reno, Nevada 89502  
[brian.erling@renown.org](mailto:brian.erling@renown.org)

**Re: Response to October 6, 2023, Notice of Intent to Terminate  
2019 Affiliation Agreement**

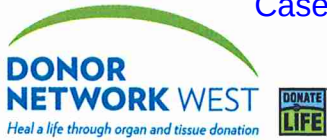
Dear Dr. Erling:

We are in receipt of a notice from you *via* certified mail on October 6, 2023, where you purport to terminate Donor Network West’s decades of effective partnership with Renown Health and the Affiliation Agreement that has been in effect since August 30, 2019 (“Agreement”). Donor Network West values its relationship with Renown Health. I write this response with the hope that you reconsider your decision, as it has already begun to cause confusion, uncertainty, and is jeopardizing the important life-saving mission of organ and tissue donations and transplantation in the Northern Nevada area.

Success within the organ and tissue donation community is built upon a network of relationships, irrespective of state boundaries. Communication is essential and at the core of these relationships and our life-saving mission. Given the long-standing relationship between Donor Network West and Renown Health, and the importance of the work we have done together, I am saddened by your notice. It is abrupt. To the extent Renown Health has any complaints or concerns about the life-saving services we offer to the residents of Northern Nevada, we have never been approached by you or informed of them. We work closely and collegially with your staff. I expected that some outreach or conversation, or at the very least an in-person meeting with you, would have predated this action. It did not.

The reason given in your notice for seeking termination of our Agreement is that Renown Health “is partnering with a Nevada-based donor network.” Donor Network West does not accept your notice as a document that terminates the Agreement under the law or the terms and conditions of the Agreement itself. Your purported actions violate both. Accordingly, your notice is invalid and rejected.





As a threshold matter, your suggestion that Donor Network West is not based in Nevada is incorrect as a matter of both law and fact.

Donor Network West is the only Organ Procurement Organization (“OPO”) designated and authorized by the U.S. Secretary of Health and Human Services to serve western Northern Nevada pursuant to the National Organ and Transplant Act (42 U.S.C. 273, et. seq.), the Uniform Anatomical Gift Act (NRS Chapter 451, et. seq.), and Medicare Conditions of Participation (42 C.F.R. Part 482, et. seq.). As such, Donor Network West has successfully served the residents of Washoe County, Carson City, Douglas County, Mineral County, Churchill County, and Humboldt County for over four decades.

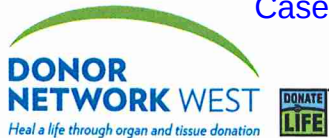
Federal law mandates that once the Centers for Medicare & Medicaid Services (“CMS”) has defined an exclusive geographic service area, *i.e.*, western Northern Nevada, and has designated an OPO for an area, *i.e.*, Donor Network West, hospitals in that area are required pursuant to the Social Security Act (42 U.S.C. 1138, et. seq.) and other federal regulations (42 C.F.R. 486, et. seq.) to work exclusively with that OPO. Hospitals must also have an exclusive written agreement with their designated OPO to identify potential donors (42 C.F.R. 486, et. seq.). Donor Network West is Renown Hospital’s designated OPO, and CMS has not changed this designation.

The policy behind this federal designation is to transcend political boundaries to match organ donors with recipients as quickly as possible. This approach—one based upon a federal designation involving an OPO’s region and geography—is embraced and practiced throughout the organ and tissue donation community. It is also the law.

Be assured, Donor Network West is Nevada-based. We operate a headquarters in Reno that employs approximately 45 experienced staff members with an estimated budget of \$4.8 million for fiscal year 2024. In June 2022, we opened a new 17,000 square foot office in Reno to continue serving the growing organ and tissue needs of Northern Nevadans.

Donor Network West partners with such entities as the University of Nevada, Reno School of Public Health; the Nevada Hospital Association; and Donate Life Nevada. We recently established the Northern Nevada Advisory Council, which is comprised of Northern Nevada community leaders and stakeholders in our mission. We have been (and continue to be) a long-term member of the Northern Nevada community. Any assertion otherwise is false.

As the second largest OPO in the nation, Donor Network West serves more than 13 million people and connects organ and tissue donors to 45 counties that are geographically interconnected and located throughout the Northern Nevada and Northern California regions. As the OPO for the region, Donor Network West provides Northern Nevadans with access to 7 transplant centers and 175 partnering donor hospitals. In addition, we



work with over 500 funeral homes and 44 coroners and medical examiners. We are the only OPO in Nevada that provides high quality and world-renowned multi-organ transplant services. We not only procure kidneys for transplants, but other life-sustaining organs, such as hearts, lungs, livers, and pancreases.

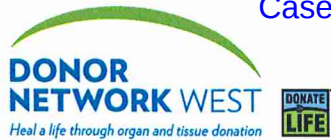
Our record of success in Northern Nevada is supported by federal data compiled by the Organ Procurement & Transplantation Network (“OPTN”) within the U.S. Department of Health & Human Services. Donor Network West’s donation rate in Northern Nevada for the year 2022 was ranked in Tier 1. We received the highest OPO ranking in Nevada. Donor Network West’s kidney recovery/discard rate for the past four years was well below the national average of 26%. We maintained the best rating of any OPO in Nevada. Over the past decade Donor Network West’s partnership with Renown Health has resulted in a 46% increase in organ donations. Donor Network West’s commitment to providing access and equitable treatment to patients is unparalleled. That Renown Health now seeks to end this relationship is unfortunate and, frankly, puzzling.

Section 10 of the Agreement expressly sets forth four limited circumstances that may support its termination, all of which are predicated on CMS action. None of them apply in this case. Your notice is therefore premature, ineffective, and fails to activate the required 90-day termination period. Only upon CMS review and approval could the “without cause” notification be effectuated. Again, this has not occurred.

Pursuant to the Agreement, as well as state and federal law, Donor Network West remains the federally-designated OPO for western Northern Nevada and Renown Health. Absent a determination by CMS, we shall continue to serve Renown Health and the residents of Northern Nevada as we have done for the past four decades. We expect that you shall continue partnering with us in good faith to meet the organ and tissue health care needs of Northern Nevadans in accordance with your contractual and legal obligations.

Rumors of Renown Health’s unprecedented notice to Donor Network West and course of action have already begun to circulate through the organ and tissue donor community. This has caused disruption and uncertainty to our life-saving mission, which, ultimately, impacts the patients and families we serve.

We request that you immediately withdraw your notice, disavow any intent to terminate our relationship, and provide written assurances to us by **5:00 p.m. Monday, October 23, 2023**, that Renown Health intends to honor its Agreement with Donor Network West and its obligations under state and federal law. Your failure to do so will result in Donor Network West pursuing legal action against Renown Health, and others, as necessary to protect the patients and communities we serve in Northern Nevada.



It remains my sincere hope that this matter can be promptly resolved without litigation, which is in no one's best interest. Please feel free to contact me directly if you would like to meet in person or further discuss this matter.

Warm regards,

A handwritten signature in blue ink that reads "Janice Whaley". The signature is fluid and cursive.

Janice Whaley  
President and CEO  
Donor Network West