1	RICHARD B. KATSKEE*	JAMES R. WILLIAMS (SBN 271253)
2	AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE	GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837)
3	1310 L Street NW, Suite 200 Washington, DC 20005	MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055)
4	Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org	H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL,
5	GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS	COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl. San José, CA 95110-1770
6	199 Water Street, 22nd Floor New York, NY 10038	Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org
7	Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org	LEE H. RUBIN (SBN 141331)
8	JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND	MAYER BROWN LLP Two Palo Alto Square, Suite 300
9	EDUCATION FUND, INC.  105 West Adams, 26th Floor	3000 El Camino Real Palo Alto, CA 94306-2112
10	Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307	Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com
11	jgliksberg@lambdalegal.org	Counsel for Plaintiffs
12	LINUTED OF ATEC 1	NETDICT COURT
13	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA	
14	COUNTY OF SANTA CLARA, TRUST	Case No. 5:19-cv-2916
15	WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC,	
16	INC. d/b/a WHITMAN-WALKER HEALTH,	DECLARATION OF LOIS BACKUS, M.P.H., IN SUPPORT OF PLAINTIFFS'
17	BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON	MOTION FOR NATIONWIDE PRELIMINARY INJUNCTION
18	HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS	
19	FOR CHOICE, AGLP: THE ASSOCIATION	
20	OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR	
21	HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ	
22	EQUALITY, COLLEEN MCNICHOLAS,	
23	ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,	
24	Plaintiffs,	
25	VS.	
26	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II,	
27	in his official capacity as SECRETARY OF	
28	HEALTH AND HUMAN SERVICES,  Defendants.	
40	n iberendants	

4 | inc

- 1. I am the Executive Director of Plaintiff Medical Students for Choice ("MSFC"). MSFC is 501(c)(3) non-profit that advocates for full integration of reproductive healthcare, including abortion and contraception, into the curricula at medical schools and residency programs. A copy of my curriculum vitae setting forth my experience, education, and credentials in greater detail is attached as Exhibit A.
- 2. MSFC is comprised of student-led chapters at medical schools, and these grass-roots, student activists are supported by the national MSFC staff, who implement programming, manage resources, and provide expertise. Medical student activists make up the majority of our Board of Directors, and the MSFC student chapters provide data and information about the state of family planning training at the local-level to guide the strategic planning of the Board.
- 3. MSFC's central mission is to expand access to health services that allow patients to lead safe, healthy lives consistent with their own personal and cultural values, including with respect to all aspects of sexual and reproductive health. MSFC furthers this mission by supporting future generations of family planning providers in accessing training in abortion and contraception.
- 4. MSFC has 163 chapters in 45 U.S. states, and another 55 chapters outside of the U.S. We have thousands of current student members across the nation.
- 5. I submit this Declaration in support of Plaintiffs' challenge to the final rule promulgated by the Department of Health and Human Services ("HHS") relating to "Conscience Rights in Health Care" (the "Rule").
- 6. Despite this considerable number of students desiring family planning training and the commonality, simplicity, and safety of outpatient abortion, most medical students do not receive training in abortion, and some do not even receive training in contraceptive care. Less than half of our members learned about first-trimester abortion from their schools.

<sup>&</sup>lt;sup>1</sup> National Academies of Science, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* 77 (2018) ("The clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective.").

- When future doctors are not educated about abortion and family planning, they are unable to offer their patients the full range of reproductive healthcare.
- Reproductive choice is only a reality for patients when there are enough family planning providers available to meet patients' needs and such providers are geographically accessible and available in an equitable distribution. Presently, the supply of such providers is not meeting the needs of American patients, in large part because facilities providing abortion are increasingly concentrated in cities, and very few primary care providers are skilled in family planning despite the continuity of care they could offer to patients, especially outside of urban areas.<sup>2</sup> Only a very small number of privately practicing OB/GYNs provide abortion in their practice, and one survey found that 35% of physicians who do not provide abortion do not refer for it either.<sup>3</sup> As threats to abortion training programs increase, this gap widens, further
- Medical schools and residency programs receive substantial funding from HHS. Teaching hospitals receive a significant majority of their training budgets from HHS. In total, HHS provides over \$10 billion per year directly and indirectly to teaching hospitals through Medicare, Medicaid, and other funding streams.<sup>5</sup> In 2018, 45 of the 50 top National Institutes of Health grant amounts were to teaching hospitals and medical education programs. Residency

25

26

27

<sup>&</sup>lt;sup>2</sup> See Susan Yanow, It Is Time to Integrate Abortion into Primary Care, 103(1) Am. J. of Pub.

<sup>21</sup> 

<sup>&</sup>lt;sup>3</sup> Desai S et al., Estimating Abortion Provision and Abortion Referrals Among United States Obstetrician-Gynecologists in Private Practice, 97(4) Contraception 297 (2018).

<sup>2014, 49(1)</sup> Persp. on Sexual & Reprod. Health 17 (2017).

<sup>&</sup>lt;sup>6</sup> Alex Philippidis, *Top 50 NIH-Funded Institutions of 2018*, Genetic Engineering & Biotechnology News (June 4, 2018), https://www.genengnews.com/a-lists/top-50-nih-fundedinstitutions-of-2018.

programs are directly subsidized by federal programs—residents receive salaries from Medicare funding, and residency programs bill to Medicare for the services of their residents.

- 10. I understand that teaching hospitals and residency programs are considered "direct recipients" under the Rule. All of the institutions and programs currently training our student members must immediately comply with the Rule if it goes into effect. Moreover, to the extent that medical students and residents are considered subrecipients under the Rule, a teaching facility may also bear responsibility for the compliance of their students or residents.
- 11. MSFC fears that the Rule will significantly incentivize the limited number of remaining programs training students and residents in abortion and contraception to discontinue family planning training. MSFC justifiably fears further and extensive reduction in training programs because it has already become aware of extensive threats to such training even prior to the promulgation of the Rule, and the Rule will provide extremely strong incentives for the remaining providers to turn away abortion patients.
- 12. The national MSFC staff works to guide its student chapters on how to acquire training in family planning and avoid pitfalls imposed by certain institutions or legal requirements constraining access to such training. We monitor the state of abortion and contraception access across the country closely so we can effectively advise our chapters, and we receive data and information about access to abortion training across the 45 states in which our chapters operate.
- 13. Even when individual students and residents are willing to be trained in abortion care and contraception, and providers are willing to provide such education and services, their institutions may restrict the services they can learn and provide on the basis of religious or moral objection. These objections have already resulted in a severe reduction in the provision of family planning services.
- 14. For example, four of the ten largest healthcare systems in the United States by hospital count are now religiously-sponsored, a circumstance attributable in part to massive hospital consolidations between Catholic systems and secular institutions. Catholic hospitals now

c

care for approximately 1 in every 6 hospital patients in the U.S.<sup>7</sup> These hundreds of hospital consolidations have led many facilities to sacrifice family planning services.<sup>8</sup>

them from providing comprehensive reproductive healthcare. For example, the U.S. Conference of Catholic Bishops has issued *The Ethical and Religious Directives for Catholic Health Care*Services, which governs all Catholic health institutions and must be adopted by any hospital wishing to merge with a Catholic facility. The *Directives* forbid doctors working in Catholic hospitals from all abortion and contraception procedures and counseling, except "natural family planning. Aside from the direct prohibition on abortion and contraception, the *Directives* significantly restrict postpartum and direct sterilization, including tubal ligation and hysterectomy, elimination of ectopic pregnancy, medical miscarriage management or other fetal loss, screening for fetal anomalies, assisted reproductive technologies like IVF, and HIV and STI prevention counseling. For example, following the merger of Swedish Medical Center ("Swedish") with Providence Health in 2012, the family medicine residency program at Swedish lost access to abortion training, and those residents have had to travel to other states to obtain it. The purchase of the Los Angeles County/University of Southern California family medicine

<sup>&</sup>lt;sup>7</sup> Lois Uttley & Christine Khaikin, *Growth of Catholic Hospitals and Health Systems: 2016 Update of the Miscarriage Of Medicine Report*, MergerWatch 1 (2016), http://statiol.loggraph.com/statio/f/816571/27061007/1465224862580/MW. Update 2016

 $http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW\_Update-2016-MiscarrOfMedicine-report.pdf?token=XlfagUpjX2g9GXDKAyqHQHDUbig\%3D.$ 

<sup>&</sup>lt;sup>8</sup> See id.

<sup>&</sup>lt;sup>9</sup> United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (6th ed. 2018).

<sup>&</sup>lt;sup>10</sup> *Id*. at 19.

<sup>&</sup>lt;sup>11</sup> See id. at 18-19; see also Uttley & Khaikin, supra note 7, at 1 ("Catholic hospitals operate under ethical directives that prohibit the provision of key reproductive health services (such as contraception, abortion, sterilization and infertility services). We documented instances in which, as a result of these directives, women suffering reproductive health emergencies — including miscarriages — have been denied prompt, appropriate treatment at Catholic hospitals." (citing United States Conference of Catholic Bishops, supra note 9)).

program by Dignity Health in 2012 (formerly known as Catholic Healthcare West) resulted in a ban on abortion training and counseling as well as a prohibition on prescribing birth control for all residents.

- 16. As a result of these mergers and other factors, it is already the case that huge regions of the country in the South and Midwest of the U.S. have deserts of abortion training where no hospitals or training programs offer abortion or contraception training.<sup>12</sup> This compounds the existing gaps in abortion and contraception access by preventing locally-training physicians from becoming skilled in providing family planning services.
- 17. In such areas, most of the limited opportunities to acquire training in family planning are offered by independent abortion clinics and Planned Parenthood affiliates. But, these facilities are themselves under tremendous strain from state restrictions in the South and Midwest. And some states, including Oklahoma, require medical students to receive training at public hospitals, none of which provide family planning training.
- 18. There is no place in the country, however, that is not already experiencing threats to abortion training accessibility based on objections to care. <sup>14</sup> We expect that many hospitals that have not already bowed to the pressure from other institutions, members of their own leadership or staff, and/or political controversy to restrict or cease the provision of abortion and contraception, will quickly self-police and cease offering these services in order avoid the possibility of failing to comply with the Rule's vague and unworkable requirements. Further, we expect this self-regulation to take place not only in the South and Midwest, but in regions of the United States where access to reproductive healthcare is often assumed to be untouchable.
- 19. Several institutions have already bowed to this pressure, demonstrating the likelihood that the Rule will lead many other institutions to self-regulate. For example, the MSFC

<sup>&</sup>lt;sup>12</sup> See Cartwright AF et al., *Identifying National Availability of Abortion Care and Distance From Major US Cities: Systematic Online Search*, 20(5) J. of Med. Internet Res. e186 (2018).

<sup>&</sup>lt;sup>13</sup> See id.

<sup>&</sup>lt;sup>14</sup> See id.

staff has spent two years working with a medical student at a major New York medical school. In 2008, this medical school simply eliminated all abortion information from the medical education curriculum because of the religious concern of a major donor who sat on the Board of the overarching health system. Since 2017, we have been assisting with producing a proposal to reimplement reproductive healthcare education for medical students at that institution. When asked by an MSFC resident, the medical students indicated that they thought the exclusion of abortion care was normal for American medical schools.

- 20. Also in New York state, an MSFC alumni treated a patient who was refused service at an emergency room while she was having a pre-viability miscarriage because a fetal heartbeat could still be detected. Although prior to viability, a completion of miscarriage procedure is the standard of care in such circumstances, individuals and institutions with religious and moral objections to abortion often treat these cases as abortion cases. She travelled to another provider, and the hospital and providers who ultimately received the patient further put her in jeopardy when the only anesthesiologist available refused to participate in the completion of miscarriage procedure, even as the patient had begun to hemorrhage.
- 21. At another major university in the Midwest, the family medicine residency program shut down the abortion training portion of their residency program because they were unwilling to risk the loss of any funding pursuant to a funding restriction that prohibited state funding for training on abortion that was passed in that state. The OB/GYN residency program, which was under separate leadership, elected to use other streams of funding to support their abortion training. Because of that, at that institution, depending on your residency program, even in the overall area of family or reproductive health, you may or may not have access to institutional abortion training due to distinctions in leadership within an overarching structure.
- 22. At another major east coast university medical school, students can rotate through a clinic for the homeless. Physicians who supervise the rotation are outspoken and anti-choice. As a result, MSFC members who performed the rotation were unable to even counsel patients about

11

12

8

13 14 15

17 18

16

19 20

22

23

21

24

25

26 27

28

contraception because the supervising physicians informed the students that such care was "upsetting" to them (the physicians).

- 23. Teaching hospitals—defined as any hospital that provides any training to residents or medical students—are the vast majority of hospitals in the United States. Many training programs also place students at other hospitals in their area. For example, another large medical school sends residents to 5 hospitals. One of these is a Catholic hospital. Based arbitrarily on where they are placed, therefore, residents may not be exposed at all to reproductive healthcare.
- 24. Catholic hospitals are also not the only religiously-affiliated hospitals that fail to provide reproductive healthcare. Other religiously-affiliated healthcare providers, including Adventist hospitals, do not provide such services. 15
- 25. A medical school in Seattle ceased its abortion training due to the adoption of the Ethical and Religious Directives and began sending residents to Colorado to receive that training. This imposed significant cost on the program. When Colorado ceased providing training, the program began to send residents to Hawai'i for training at an even greater cost. Few programs will be this committed to training in abortion care.
- 26. We are familiar with numerous other instances of providers referring to our alumni because they were not allowed to provide the abortion care or contraceptive care needed by a patient at their institution. Even patients seeking to terminate wanted pregnancies due to fetal anomalies or experiencing miscarriage struggle to obtain care if they come across a provider who either refuses to assist or refuses even to provide them with a referral or any other kind of information.
- Recently, an MSFC alumnus was called in to perform a therapeutic abortion in the 27. second trimester for a patient whose life was endangered by her pregnancy. The hospital treating the patient did not have any trained physicians, and had to bring in an outside physician at considerable expense. These types of costs are also typically passed onto the patient.

<sup>&</sup>lt;sup>15</sup> Amy Littlefield, Meet Another Religious Health System Restricting Reproductive Care, Rewire (Jan. 30, 2019), https://rewire.news/article/2019/01/30/meet-another-religious-health-systemrestricting-reproductive-health-care.

- 28. To the extent that the Rule forces an institution of medical education to comply with onerous and unworkable rules at the risk losing the majority of its funding, we believe that many facilities will simply remove abortion and contraception from their curricula. There are numerous individuals involved in patient care at a major hospital—those responsible for scheduling, cleaning, testing—all before you get to the medical staff. If, under the Rule, all of these people are empowered to delay or deny care or information related to abortion or contraception based on their own beliefs, and the hospital is powerless to intervene without risking loss of all federal funding, the Rule will impose innumerable harms on both patients and healthcare facilities. Rather than risk the loss of funding or an ethical and malpractice crisis related to patients denied and delayed access to care, even in an emergency, many facilities will self-regulate and eliminate contraceptive and abortion services.
- 29. Aside from the loss of training opportunities for our student and resident members, such a reduction in access to abortion and contraception training will impose significant harm on MSFC as whole by placing even greater strains on our already thinly stretched resources, which even today are insufficient to train all those who need such training outside of their institutions.
- 30. MSFC alumni are among the shrinking pool of abortion providers across 42 states. These alumni are the primary faculty at our educational programs. We have two sets of programs that we operate for our members who cannot acquire abortion training at their home institutions.
- 31. First, we run educational seminars that offer intensive education on family planning over several days. We can accept fewer than 500 students a year based on our current budget. This intensive education gives students a full picture of family planning as well as the social and political barriers they may face when seeking to become abortion providers. We also provide abortion training institutes for smaller groups of students. Acceptance to these institutes is competitive. We can accept fewer than 50% of those who apply.
- 32. Second, we run externship programs through independent clinics and Planned Parenthood affiliates. With the help of these strong allies, we are able to give some of our members a view into the day-to-day provision of care. Our members report that their externship is

mind-opening—not because abortion is controversial—but precisely because of how simple and safe the procedure actually is. Members also have an opportunity to hear the stories of patients seeking abortion first-hand. This externship program is more difficult for residents, as compared with medical students, because they are insured through their training institution's malpractice program, and they must have approval to participate in the program. Residents also have less flexibility in their schedule, and those that are able to take advantage of the program typically do so on vacation or during off-hours.

- 33. Further complicating the program, the number of clinics providing abortion care is dwindling. According to the most recent data from 2014, the number of facilities in the United States that held themselves out as providers of abortion care on a regular basis has markedly decreased. Almost 90% of counties in the United States do not have an abortion clinic at all, and several states have only one clinic left in the entire state.
- 34. We financially assist students and residents participating in our training. We typically expend \$1,000 to \$2,000 per student or resident. These monies are spent on travel, accommodations, administrative fees, and any temporary licensing fees for receiving medical training outside a participant's home state. In total, we are currently spending in excess of \$100,000 annually on these expenses, a substantial amount of money for our organization. We anticipate that the Rule could at least double the amount of money we need to spend, and therefore raise, in order to meet the anticipated increase in demand for training opportunities.
- 35. Although MSFC offers a number of training programs, the existing programs already are unable to meet the need.

<sup>&</sup>lt;sup>16</sup> The number of U.S. abortion-providing facilities declined 3% between 2011 and 2014 (from 1,720 to 1,671). Jones & Jerman, *supra* note 4. The number of clinics providing abortion services declined 6% over this period (from 839 to 788). *Id*.

<sup>&</sup>lt;sup>17</sup> *Id*.

<sup>&</sup>lt;sup>18</sup> Bad Medicine: How a Political Agenda is Undermining Abortion Care and Access, National Partnership for Women & Families (Mar. 2018), <a href="http://www.nationalpartnership.org/research-library/repro/bad-medicine-third-edition.pdf">http://www.nationalpartnership.org/research-library/repro/bad-medicine-third-edition.pdf</a>.

- 36. Starting about ten years ago, MSFC began monitoring the impact of efforts to protect individual conscience at the expense of abortion training and patients' access to abortion. MSFC is part of a coalition of groups, including Catholics for Choice and various LGBTQ organizations, that focuses on religious refusals and "conscience rights" around the country. We stay in close contact with this coalition, so we can stay abreast of removals of abortion training and other threats to abortion access at teaching facilities across the country. MSFC has started to train students and residents on the impact of religious and moral refusals in the provision of family planning as well.
- 37. I have been in reproductive and community healthcare in some form my whole career. I completed a Master of Public Health at Yale, and I spent many years as the Executive Director of Planned Parenthood affiliates.
- 38. To the extent that the Rule enables almost any hospital staff-person, including some non-medical staff, to refuse to take any action related to an abortion, contraception, or other objected-to care, even in an emergency and without informing the patient, it is the broadest expansion of "conscience rights" that I and MSFC generally have seen or could have anticipated. Were it to take effect, the Rule would be impossible for a hospital to practically implement. Hospitals that provide abortion or have provided abortion already struggle to maintain patient care with medical staff refusing to assist with patients in need of care, as described above.
- 39. If the Rule goes into effect, the U.S. will see an even more dramatic reduction in the already dwindling number of medical-education institutions where abortion is regularly provided and taught to students and residents. Family planning training in the U.S. is already suffering; and the Rule will immeasurably exacerbate the problem.
- 40. MSFC would have to try to bridge the gap for highly motivated students. This would mean educating thousands of students a year. There will be many students who we cannot accommodate, and likely many more who will simply give up.
- 41. We already exist in a national medical system in which most licensed family medicine doctors and OB/GYNs are completely ignorant of both abortion, one of the most

common and extremely safe reproductive procedures for women, and many forms of contraceptive counseling.

- 42. At MSFC, we believe that licensed physicians have an obligation to serve the needs of their patients. This means that physicians who object to providing care must ensure that their objection does not inhibit the patient from ultimately getting the care that they need in a timely manner. When a provider's personal beliefs conflict with a patient's need for care, medical ethics as well as state and federal law require the needs of the patient to take precedence. Within the medical community, this bedrock principle is clear and well-accepted *outside of the provision of abortion care*, but compromised with respect to family planning, despite the opinions of major medical organizations that this ethical principle is particularly essential in reproductive healthcare.<sup>19</sup>
- 43. If this Rule goes into effect, abortion may simply fall out of mainstream medical education, and once a medical practice is removed, it may take years to reintroduce it into a complex hospital system.
- 44. Anti-abortion laws and campaigns have heavily stigmatized abortion and contraception,<sup>20</sup> and the professionals who providers these services.<sup>21</sup> Already, our students face incredible stigma when they relate their interest in becoming abortion providers. In many cases,

<sup>&</sup>lt;sup>19</sup> See, e.g., American College of Obstetricians and Gynecologists Committee on Ethics, Committee Opinion No. 385: The Limits of Conscientious Refusal in Reproductive Medicine, 110 Obstetrics & Gynecology 1203 (2007) ("Physicians and other health care providers have the duty to refer patients in a timely manner to other providers if they do not feel that they can in conscience provide the standard reproductive services that patients request."); American Medical Association, Code of Medical Ethics Opinion 1.1.7: Physician Exercise of Conscience, Ethics, https://www.ama-assn.org/delivering-care/physician-exercise-conscience (last visited June 6, 2019) ("In general, physicians should refer a patient to another physician or institution to provide treatment the physician declines to offer.").

<sup>&</sup>lt;sup>20</sup> See Norris A et al., Abortion stigma: a reconceptualization of constituents, causes, and consequences, 21(3 Suppl) Women's Health Issues S49 (2011); Smith W et al., Social Norms and Stigma Regarding Unintended Pregnancy and Pregnancy Decisions: A Qualitative Study of Young Women in Alabama, 48(2) Persp. on Sexual & Reprod. Health 73 (2016).

<sup>&</sup>lt;sup>21</sup> See Norris, supra note 20; Freedman L et al., Obstacles to the integration of abortion into obstetrics and gynecology practice, 41(3) Persp. on Sexual & Reprod. Health 146 (2010).

# Case 5:19-cv-02916-NC Document 36-1 Filed 06/11/19 Page 13 of 16

1	once a physician has "outed" themselves as an abortion provider, they become isolated from the		
2	mainstream.		
3	45. This Rule institutionalizes this isolation and will make it impossible even for many		
4	highly motivated MSFC members to acquire training. The result, should the Rule go into effect,		
5	will be compromised access to reproductive healthcare and staggering health consequences for		
6	patients across the nation.		
7	I declare under penalty of perjury under the laws of the United States of America that the		
8	foregoing is true and correct.		
9	Dated: June 6, 2019 Respectfully submitted,		
10			
11	/s/ Lois Backus		
12	Lois Backus, M.P.H., Executive Director Medical Students for Choice		
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28	- 12 -		
	DECLARATION OF LOIS BACKUS, M.P.H., ISO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION CASE NO. 5:19-CV-2916		

# EXHIBIT A

Lois V. Backus, M.P.H.

Medical Students for Choice PO Box 40935 Philadelphia, PA 19107 215-625-0800 lois@msfc.org

**Lois V. Backus, MPH** has been a non-profit chief executive in the reproductive health field for 30 years, with more than 17 years as the leader of Medical Students for Choice, an organization supporting the education and training of medical students in abortion.

## **Executive Experience -- 1989 through Today**

2001 to present Medical Students for Choice

Philadelphia, PA

**Executive Director**, responsible for leading an international, grassroots organization of more than 10,000 medical student activists worldwide who are working to make family planning a standard part of medical education and training. Primary programs include supporting 163 medical school chapters in the US and 60 chapters in 24 other countries with educational materials, funding, and training conferences in the US.

- Developed training conferences focusing on filling gaps in medical curricula pertaining to abortion, including the annual Conference on Family Planning and the Abortion Training Institutes. These training programs serve more than 500 US medical students each year.
- Expanded the Reproductive Health Externship Funding Program which places medical students in abortion-providing facilities for an intensive 2 to 4 week educational experience. This program serves between 180 and 200 medical students per year.
- Sustained and expanded MSFC's chapters from 96 to over 200 chapters.

#### 1996-2001 Planned Parenthood of the Columbia/Willamette Portland, OR

**Executive Director,** responsible for all aspects of a 115 employee non-profit women's health and advocacy organization, with headquarters and six satellite facilities across Oregon and southwest Washington.

- Expanded the services provided in the flagship clinic to include reproductive surgeries for both men and women.
- Worked closely in collaboration with other social justice organizations to successfully fight ballot measures that would have hindered vital access to health services.
- Developed local community groups to support the expansion of government subsidized family planning services for the underserved in rural communities across Oregon.
- ) Opened three new facilities providing abortions, including establishing the first independent, comprehensive women's health clinic in central Oregon.

#### 1989-1996 Planned Parenthood of Central Pennsylvania York, PA

**Executive Director,** responsible for leading a non-profit women's health organization serving York County, Pennsylvania. During these seven years, nine new services were added, including abortion services.

#### Education

**M.P.H.,** Yale University School of Medicine, Department of Public Health, New Haven, CT. **A.B.,** Political Science and Religion, Mount Holyoke College, South Hadley, MA.

Lois V. Backus, M.P.H. 2

## **Other Relevant Experience**

1988-1989 **Toltzis Communications** 

Glenside, PA

**Project Manager** Developed healthcare communications solutions for a marketing firm serving the pharmaceutical industry.

1987-1988 Abington Memorial Hospital

Abington, PA

**Coordinator, Community Health Education** Provided medical screening and health education to a community of 100,000 people, including planning and implementing large community events.

1985-1987 **People's Medical Society** 

Emmaus, PA

**Director of Policy Affairs** Managed a nationwide grassroots organizing project focused on health care access for seniors.

1983-1984 Community Treatment Complex

Worcester, MA

**Program Coordinator** Managed a residential treatment program for emotionally disturbed adolescents.

1980-1982 Centers for Disease Control

Nashville, TN

Public Health Advisor Coordinated a federal sexually transmitted disease tracking program.

1978-1979 **Peace Corps** 

Kabul, Afghanistan

Volunteer Teacher Taught English and Business Mathematics to vocational college students.

1	RICHARD B. KATSKEE*	JAMES R. WILLIAMS (SBN 271253)
2	AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE	GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837)
	1310 L Street NW, Suite 200	MARY E. HANNA-WEIR (SBN 320011)
3	Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234	SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756)
4	katskee@au.org	OFFICE OF THE COUNTY COUNSEL,
5	GENEVIEVE SCOTT*	COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl.
6	CENTER FOR REPRODUCTIVE RIGHTS 199 Water Street, 22nd Floor	San José, CA 95110-1770
6	New York, NY 10038 Tel: (917) 637-3605; Fax: (917) 637-3666	Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org
7	gscott@reprorights.org	LEE H. RUBIN (SBN 141331)
8	JAMIE A. GLIKSBERG*	MAYER BROWN LLP Two Palo Alto Square, Suite 300
9	LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.	3000 El Camino Real
10	105 West Adams, 26th Floor	Palo Alto, CA 94306-2112 Tel: (650) 331-2000; Fax: (650) 331-2060
10	Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307	lrubin@mayerbrown.com
11	jgliksberg@lambdalegal.org	Counsel for Plaintiffs
12		
13	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA	
14		
	COUNTY OF SANTA CLARA, TRUST WOMEN SEATTLE, LOS ANGELES LGBT	Case No. 5:19-cv-2916
15	CENTER, WHITMAN-WALKER CLINIC,	DECLARATION OF ELIZABETH
16	INC. d/b/a WHITMAN-WALKER HEALTH,	BARNES IN SUPPORT OF
17	BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON	PLAINTIFFS' MOTION FOR NATIONWIDE PRELIMINARY
18	HALSTED, HARTFORD GYN CENTER,	INJUNCTION
	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION	
19	OF LGBTQ+ PSYCHIATRISTS, AMERICAN	
20	ASSOCIATION OF PHYSICIANS FOR	
21	HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ	
22	EQUALITY, COLLEEN MCNICHOLAS,	
	ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,	
23	Plaintiffs,	
24	,	
25	vs. U.S. DEPARTMENT OF HEALTH AND	
26	HUMAN SERVICES and ALEX M. AZAR, II,	
	in his official capacity as SECRETARY OF	
27	HEALTH AND HUMAN SERVICES,	
28	Defendants.	

8

13

17

18

16

19 20

22 23

21

24 25

26

27

28

I, Elizabeth Barnes, declare as follows:

- 1 I am the President of The Women's Centers, a group of reproductive healthcare clinics in the Northeast of the United States that provides abortion care and contraception, among other services.
- 2. The Hartford Gyn Center in Hartford, Connecticut is one such clinic. It opened in 1978, and is the only independent, state-licensed family-planning clinic in the State of Connecticut. The clinic also operates a medical residency rotation program.
- 3. I submit this Declaration in support of Plaintiffs' challenge to the final rule promulgated by the Department of Health and Human Services ("HHS") relating to "Conscience" Rights in Health Care" (the "Rule") and the Rule's enforcement by the HHS Office of Civil Rights ("OCR").
- 4. Hartford Gyn's mission is to provide women with compassionate abortion care. We provide abortion through 21 weeks of pregnancy as well as other reproductive health services. In carrying out this mission, the autonomy of each patient is paramount. The clinic's practices are designed to support patients in making their own healthcare decisions free from external judgment. The clinic also advocates for the reproductive rights of all patients and seeks to effect corresponding social change.
- 5. Hartford Gyn is a subrecipient of federal Medicaid funding through the state of Connecticut. I understand that, as a result, Hartford Gyn will be considered a "subrecipient" under the Rule.
- 6. Connecticut is one of the states that permits the use of state Medicaid funding for elective abortions, with this funding separated from federal dollars also flowing through the state program, which can be used to reimburse non-abortion services.
- 7. In 2017, Medicaid funding accounted for 70 % of Hartford Gyn's income. Private insurance covered only 17 %, and cash payment and donations from abortion funds made up the remaining 13 %. While the clinic has not yet finalized these figures for 2018, they will remain at approximately these levels.

- 10
- 12
- 14

- 18
- 19

- 26
- 27 28

- 8. Abortion services accounted for 66 % of Hartford Gyn's services in 2017. The remaining 34 % included contraception and a small amount of gynecological care. Although federal Medicaid dollars do not cover our abortion services, approximately half of the reimbursement we receive for our contraception and gynecological services originates with HHS.
- 9. Hartford Gyn's survival depends on the receipt of Medicaid funding, in part, because it receives so few patients who pay for their services privately or are covered by private insurance. Given the number of hospital facilities and individual physicians who provide gynecologic services in Connecticut for privately-paying patients, and the fact that the state Medicaid program reimburses providers for abortions and other services, it is impossible that Hartford Gyn would ever be able to rely on privately-paying patients to make up for the loss of federal Medicaid dollars. Reimbursement for gynecological services, a small percentage of our services, would also be insufficient to make up for the loss of federal Medicaid funding. At present, the clinic is barely sustained by the income generated by its current patient population. We exist, not for economic gain, but to pursue our mission of serving women in need of reproductive healthcare, including abortion and contraception.
- 10. Hartford Gyn would close quickly if it could not receive even a small percentage of its current income and would certainly close if we lost the sizable reimbursement we receive for contraception services. The clinic has no reserve funding, and clawback of any amount would bankrupt the business.
- 11. To the extent that the Rule prevents the clinic from expecting that staff members interact with all patients without judgment, would permit staff to unilaterally deny patients care and information, or force us to forego our emergency services and staffing practices, it is contrary to our mission and unworkable.
- 12 If it takes effect, the Rule will impose immediate administrative costs. Under the Rule, the clinic must maintain records of its compliance, although the Rule does not specify the exact form of these records.
- 13. The clinic will also be subject to investigation or inspection, measures which can be initiated unilaterally by HHS based on a complaint or even in the absence of a complaint. The

Rule is silent as to whether HHS must inform the clinic of an investigation or follow any particular procedure with respect to these investigations or inspections. The Clinic must cooperate with these measures; although the Rule is also silent as to the specific requirements of such cooperation. Further, the Rule states that HHS "shall" inspect any clinic based on any complaint or other information indicating an actual, possible, or threatened violation of the Rule. The Rule specifies that patient privacy is not grounds for denying access to records, even, apparently, patients' unredacted medical records.

- 14. If OCR finds a violation of the Rule, with or without a complaint, OCR is empowered to withdraw or even clawback our Medicaid funding. I understand that under the Rule, Connecticut's Medicaid program as the direct recipient also bears primary responsibility for our compliance with the Rule, incentivizing the state to fund less reproductive healthcare out of fear that the state might lose its federal funding. I further understand that under the Rule, the conduct or activity of contractors is "attributable" to the state for the purposes of enforcement or liability under the Weldon Amendment, further disincentivizing continued funding to the clinic. Loss of funding would shutter the clinic.
- 15. Hartford Gyn is unique even among clinics in progressive states for a number of reasons that would make its closure extremely burdensome for patients and providers.
- 16. First, Hartford Gyn has a broad depth of physician experience and provides advanced care, including abortion through 21 weeks of pregnancy, not provided by other facilities in the area. The clinic also employs a certified nurse-anesthetist, a specialized nurse that is rare and expensive. Hartford Gyn is the only independent abortion provider in Connecticut and the only non-hospital provider offering abortion care services past 19 weeks of pregnancy. Although hospital services may be available at some facilities, high cost and limited appointment availability can push this care out of reach for many people.
- 17. Second, Hartford Gyn sees patients from all walks of life, including low-income patients who cannot easily access care elsewhere, if at all. Hartford Gyn serves a large number of low-income patients, many of whom rely on Medicaid insurance, funding support, and/or discounted services at the clinic to access care. Further, many of Hartford Gyn's patients often

face difficulties taking time from work, coordinating affordable transportation, and accessing childcare—additional barriers to healthcare access. If Hartford Gyn were forced to close, patients who rely on the clinic for care will be forced to travel further the access care, compounding the logistical and financial challenges they face in accessing care, and preventing some from accessing care altogether, with disproportionate impacts on low-income patients.

- 18. Third, Hartford Gyn is one of the only facilities in the region that trains physicians in abortion care, especially in the second trimester. Although it does not receive significant outside funding for this training, it provides this service based on its deep commitment to supporting the next generation of providers. Currently, residents at Saint Francis Hospital and Medical Center can receive training from our medical director on Saturdays.
- 19. Fourth, Hartford Gyn has taken a public stance defending reproductive rights, including in media coverage of the clinic after a "crisis pregnancy center" opened just 30 feet from our office, in the same complex, and our clinic painted a "yellow brick road" for patients to follow when entering the clinic. The clinic is a symbol of the determined provision of constitutionally-protected care in the face of adversity for the reproductive rights movement, and, correspondingly, a known target of anti-abortion activists.
- 20. Anti-choice protestors target our clinic regularly. They have intimidated and threatened providers and patients at Hartford Gyn, and have misinformed and shamed our patients right outside of our clinic. Staff routinely enter the facility briskly out of fear the anti-choice protestors on the sidewalk or in our courtyard will photograph them, track their vehicle, or cause violence, and some staff have even been targeted at their homes. Further, according to data collected by the Feminist Majority Foundation, clinics located near a crisis pregnancy center were more likely to experience high levels of violence, threats, and harassment. Anti-choice extremists have bombed clinics, killed providers and staff, threatened and exposed the personal information of providers and staff, and shamed and humiliated patients. Those who provide this care live under constant threat.
- 21. For these reasons, the careful screening of potential staff members before hiring is an essential security precaution at Hartford Gyn. Like that of most private companies, the goal of

an effective background check is to provide an accurate assessment of the applicant's qualifications. As an abortion provider, however, we also assess additional material related to an applicant's reputation, reliability, truthfulness, and objectivity based on the very real concern that an anti-abortion extremist could harm the clinic. We also work to ensure that the patient will be provided care by someone who supports their right to make decisions about their own healthcare and will treat patients in a nonjudgmental and supportive manner. This robust process contributes to the substantial administrative and staff resources expended by facilities providing abortion care services. The Rule creates an opening for anti-abortion extremists to infiltrate and incapacitate our clinic by undermining this process and creating threats to security as well as to the basic right of the patient to non-judgmental supportive care in a safe environment that protects their quality of care, confidential medical information, and dignity.

- 22. Because our clinic's mission is to provide access to reproductive healthcare services, for all staff and virtually all others working at the clinic, such as contracted cleaning staff, working at Hartford Gyn necessarily involves some kind of connection to abortion care or contraception, and the clinic procedures and practices are designed to ensure our patients receive the highest quality, non-judgmental care. The clinic must operate efficiently due to its already limited income, but in order to do so, all staff must perform functions that touch on the provision of abortion and/or contraception. For example, receptionists' job duties include scheduling patients for abortion and contraception appointments. Similarly, our bookkeeper's job duties include preparing billing for all of the services we provide. There is no alternative human resources structure that could sustain the clinic. To the extent that the Rule would force us to change our structure, we would be forced to close.
- 23. Similarly, if individual staff could delay or deny care or give incomplete information about medical options based on their own beliefs, our clinic could not function properly, particularly in emergency situations. Such actions would disrupt our mission by failing to honor the beliefs and choices of our patients and by breaking down the trust central to our model of care and to the sustainability of our business.

28

25

26

- 24. In addition to the staffing and policy issues discussed above, the Rule will create tremendous uncertainty. Because the Rule is written so broadly, we are unable to determine what our rights and our obligations are under the Rule on the day it goes into effect. Given the Rule's breadth and lack of clarity, we cannot accurately predict what we must do to comply, particularly in an emergency, while maintaining our mission and the quality of our patient care. The Rule puts the clinic in an untenable and unacceptable position.
- 25. If we cannot seek to ensure that our patients receive compassionate, non-judgmental care from every person they encounter in the clinic, we will no longer serve our central purpose.
- 26. That purpose is to provide essential reproductive healthcare services, including abortion and contraception, in a time when such care is stigmatized and threatened in the United States. The many barriers to care now inherent in healthcare systems—legal restrictions, funding limitations, stigma, among others—can be insurmountable. For many of our patients, Hartford Gyn is the provider of last resort.
- 27. We strive to empower patients to make their own, autonomous choices. We believe that respecting women's autonomy builds stronger communities and positive social change. This belief inspires our patient-centric approach to care. In order to empower patients to make decisions that support their health and are best-suited for them, we must provide comprehensive, medically-accurate information about our patients' medical options. To that end, we train and expect our staff to support patients with the resources, tools, and medical services they need to realize their choices.
- 28. When patients arrive at Hartford Gyn, they often comment on the kindness and compassion of the staff and the holistic care we provide. This response is often in some part the result of previous ill-treatment at crisis pregnancy centers or other healthcare facilities.
- 29. For example, last year, a 21-year-old patient scheduled an appointment with Hartford Gyn. On her way to her appointment, the patient and her mother were instructed to enter Hartford Women's Center, the crisis pregnancy center that opened next to our clinic. An employee of the crisis pregnancy center told the patient and her mother to "come in here" and

then proceeded to tell her that if she had an abortion, she would be "sinning" and that she "might not make it out alive." After wasting significant time, being misinformed about numerous aspects of abortion care, and treated with hostility and condemnation, they were ultimately told that "[t]here is no abortion center here." Unlike countless other patients faced with the same misinformation, the patient was able to find her way to her appointment. Once at Hartford Gyn, the patient reported feeling shame and fear. Our staff spent time with the patient to explain that she had spoken with someone who was not a medical professional and who had given her false information. This patient expected and was entitled to unbiased, non-coercive pregnancy counseling and abortion care from medical professionals.

- 30. Many patients face similar barriers to reproductive healthcare even at legitimate healthcare institutions, including Catholic hospitals. For an increasing number of communities, the closest or only hospital is a Catholic hospital operating under the guidance of the *Ethical and Religious Directives for Catholic Health Care Services* which govern certain practices at Catholic hospitals. Our patients frequently report that after presenting to their closest emergency room for evaluation, a positive pregnancy test was met with "congratulations!" and a refusal to provide requested resources or referrals to a center that would offer abortion care services. This refusal to provide comprehensive options and referrals causes delays in accessing time-sensitive abortion care, instills shame and fear in patients, and threatens severe health consequences.
- 31. Even at secular hospitals, there are often limits on the scope of care that is provided, either because of the refusal of an official in power or due to a lack of commitment to providing comprehensive reproductive healthcare, which is often accompanied by an assumption that care will remain available at independent providers like Harford Gyn.
- 32. Women seeking abortion and contraception, and the providers of such care, have been vilified in many places in the U.S. Anti-abortion activists have caused immeasurable harm, including killing abortion providers, threatening patients, infiltrating clinics, and spreading false information about patients, providers, and reproductive healthcare options, among other security concerns.

# Case 5:19-cv-02916-NC Document 36-2 Filed 06/11/19 Page 9 of 9

- 1			
1	33. Hartford Gyn serves a special role in the provision of abortion care locally and		
2	nationally, and it is particularly vulnerable to closure if it loses its Medicaid funding. The		
3	community and the broader public consider Hartford Gyn to be a responsible and trustworthy		
4	medical provider because we have provided nonjudgmental, objective, and compassionate care to		
5	women for four decades.		
6	34. We will not continue to operate if we cannot follow our best practices to avoid		
7	further harm to and further stigmatization of patients seeking reproductive healthcare. To the		
8	extent that the Rule is inconsistent with the practices that protect our patients' health, ensure		
9	nondiscrimination, and make it financially and logistically feasible to operate, we will be forced		
10	to risk the loss of all funding and closure.		
11	I declare under penalty of perjury under the laws of the United States of America that the		
12	foregoing is true and correct.		
13			
14	Dated: June 5, 2019 Respectfully submitted,		
15			
16	/s/ Elizabeth Barnes		
17	Elizabeth Barnes, President The Women's Centers		
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			

1 2 3	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200 Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837) MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756)
4	katskee@au.org	OFFICE OF THE COUNTY COUNSEL,
5	GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS	COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th F1. San José, CA 95110-1770
6	199 Water Street, 22nd Floor New York, NY 10038	Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org
7	Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org	LEE H. RUBIN (SBN 141331)
8	JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND	MAYER BROWN LLP Two Palo Alto Square, Suite 300
9	EDUCATION FUND, INC. 105 West Adams, 26th Floor	3000 El Camino Real Palo Alto, CA 94306-2112
10	Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307	Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com
11	jgliksberg@lambdalegal.org	Counsel for Plaintiffs
12		
13	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA	
14	COUNTY OF SANTA CLARA, TRUST	
15	WOMEN SEATTLE, LOS ANGELES LGBT	Case No. 5:19-cv-2916
16	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH,	DECLARATION OF ROBERT BOLAN, MD, CHIEF MEDICAL OFFICER, LA
17	BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON	LGBT CENTER, IN SUPPORT OF
18	HALSTED, HARTFORD GYN CENTER,	PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
19	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION	
20	OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR	
21	HUMAN RIGHTS d/b/a GLMA: HEALTH	
22	PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS,	
	ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,	
23	Plaintiffs,	
24	vs.	
25	U.S. DEPARTMENT OF HEALTH AND	
26	HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF	
27	HEALTH AND HUMAN SERVICES,	
28	Defendants.	

2

4 5

6 7

8

9 10

11

12 13

14

15 16

17

18 19

20

21 22

23

24

25 26

28

27

I, Robert Bolan, declare as follows:

- 1. I am the Chief Medical Officer and Director of Clinical Research for the LA LGBT Center. I oversee all medical care related services at the LA LGBT Center, as well as maintain a panel of patients for whom I provide direct care. In addition, I oversee the LA LGBT Center's Research Department, am the principal investigator for multiple HIV treatment and prevention trials, and have written and presented extensively on various matters related to the care and treatment of people living with or at risk of acquiring HIV and other sexually transmitted infections (STIs). I am also Clinical Associate Professor of Family Medicine at the University of Southern California (USC) – Keck School of Medicine, and an Adjunct Clinical Professor of Pharmacy Practice at the Western University of Health Sciences. I received my medical degree from the University of Michigan Medical School, interned at St. Mary's Hospital Medical Center, and completed my residency at St. Michael Family Practice Residency. I was the Director of HIV Services in the Department of Family Medicine at the USC Keck School of Medicine, and I have been honored with the Leadership Award from the San Francisco AIDS Foundation. I maintain active board certification with the American Board of Family Physicians and specialty certification with the American Academy of HIV Medicine. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction to prevent the Denial-of-Care Rule from going into effect.
- 2. As the Chief Medical Officer, I oversee the delivery of healthcare for approximately 9000 patients who come to the LA LGBT Center and have a panel of approximately 300 patients for whom I personally provide medical care. Over 90% of my patients identify within the LGBTQ communities. My patient population is also disproportionately low-income and experiences high rates of chronic conditions, homelessness, unstable housing, trauma history, and discrimination and stigmatization in healthcare services. Many of these patients come to me from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.
- 3. Our healthcare services span the full spectrum of primary healthcare services, including, but not limited to, HIV treatment and testing, treatment and prevention of sexually

10 11

9

13 14

12

15 16

17 18

20 21

19

22 23

24 25

26

27 28 transmitted infections, as well as treatment for gender dysphoria, mental-health disorders, and substance-use disorders.

- 4. Many if not most of the individuals in our very diverse patient population face considerable stigma and discrimination – as people living with HIV, as sexual or gender minority people, as people of color. In addition, there is a very high incidence of other social determinants of poor health outcomes among our population. These include homelessness, food insecurity, lack of access to transportation, and lack of employment opportunities.
- 5. Furthermore, there is every reason to believe that the Denial-of-Care Rule will encourage healthcare providers and staff to claim the absolute right to refuse care or opt out of serving patients with particular needs, based on personal beliefs, which will result in more discrimination against LGBT patients and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other healthcare facilities outside the LA LGBT Center. I, and the other providers that I supervise at the Los Angeles LGBT Center, have many patients who have experienced traumatic stigma and discrimination – based on their sexual orientation, gender identity, HIV status, and/or other factors – even before the Denial-of-Care Rule was proposed or issued. Based on the stories that my patients have shared with me, this discrimination, mistreatment, and denial of healthcare services has been motivated by the personal moral or religious beliefs of other healthcare providers and staff outside of the LA LGBT Center.
- 6. Over the twenty years I have been at the Center I have listened to the stories of countless individuals who have suffered overtly homophobic remarks from healthcare providers and who were either refused care or given clearly inadequate and inappropriate care because of their sexual orientation or gender identities. One of the most egregious examples was a transgender woman who needed extensive surgery to repair diffuse damage done by silicone injections into her breasts several years earlier. In 2009, she was turned away from an academic plastic surgery center in Los Angeles after the surgeon said her problem was caused by her own poor decision-making and she would therefore not be considered for treatment.
- 7. Incidents like this reveal that many healthcare providers and other staff harbor explicit or implicit biases against LGBT people. Because of legal requirements, healthcare

facility non-discrimination policies, and professional norms, many of them have kept their personal beliefs and feelings in check. By empowering healthcare staff to think that they have the legal right to act on their personal beliefs, even at the expense of patient needs, the Denial-of-Care Rule is very likely to result in many more incidents of discrimination and greater harm to LGBT individuals struggling with mental-health or substance-use issues, including the patients whom I treat and whose treatment I supervise.

- 8. Such experiences are not only insulting and demoralizing for the patient, but can jeopardize the patient's health, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many if not most of my and the LA LGBT Center's transgender patients express strong distrust of the healthcare system generally and are reluctant to seek care outside the LA LGBT Center unless they are in a crisis or in physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers.
- 9. In the case of the transgender woman I described above, her general medical condition gradually deteriorated over the several years it took for me to finally identify a surgeon who would take her case. She was suffering from systemic metabolic complications from the chronic inflammation and skin breakdown caused by the hardened subcutaneous silicone injections. I feared for her survival. Fortunately, the surgeon who cared for her did so with kindness, respect, and compassion, and the patient has had an excellent result. The surgeon saved her life. Nevertheless, the ultimate tragedy in my patient's case was that after the humiliating and callous abuse to which she was subjected by the academic center's specialists, she was completely unwilling to even consider seeing another surgeon for the next six-and-a-half years. Her suffering during that time was completely avoidable had she been treated with basic human respect.
- 10. With existing health and healthcare disparities affecting the LGBTQ community particularly the shortage of LGBTQ/HIV culturally competent providers the Denial-of-Care

27

28

Rule's vague and confusing language will further exacerbate existing barriers to healthcare and result in negative community health outcomes. Good medical care is based on trust as well as frank and full communication between the patient and their provider. In many, if not most encounters, providers need patients to fully disclose all aspects of their health history, sexual history, substance-use history, lifestyle, and gender identity in order to provide appropriate care for the patients' health, both physical and mental. Incomplete communication, or miscommunication, can have dangerous consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers; and a patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). Patients need to be encouraged to fully disclose all information relevant to their healthcare and potential treatment, which can only be achieved when patients are assured that the information they provide will be treated confidentially and with respect. The Denial-of-Care Rule endangers the provider-patient relationship, and is likely to harm many patients' health, by discouraging patients from full disclosure, and by encouraging providers to avoid topics that may offend their personal moral or religious beliefs in their encounters with patients.

11. The Denial-of-Care Rule will cause LGBT patients and patients living with HIV to lose trust in their healthcare providers (either out of fear of discrimination or on account of being denied care on religious grounds). The Rule will cause LGBT patients to attempt to hide their LGBT identities to an even greater degree when seeking healthcare services, especially from religiously-affiliated healthcare organizations, in order to avoid discrimination. The Denial-of-Care Rule endangers the provider-patient relationship, and is likely to harm many patients' health, by discouraging patients from full disclosure about their gender identity, sexual orientation, or related medical histories. Patients will avoid raising any topics, questions, facts that they fear could possibly offend their healthcare providers' personal beliefs, resulting in harm to patients.

- 12. The Denial-of-Care Rule is also likely to cause an increase in demand for my healthcare services because I have seen a spike in behavioral and mental-health issues resulting from religious or moral-based discrimination and denials of healthcare services.
- 13. The Denial-of-Care Rule is in direct conflict with the oath I swore as a doctor and many of the federal, state, and insurance rules, regulations, and statutes that I am required to follow. This has personally caused me great confusion and stress as it is unclear how I can work collaboratively with my colleagues who discriminate against or deny care to my patients without violating either current ethical and legal standards or the Denial-of-Care Rule.
- 14. As a healthcare provider with the LA LGBT Center, I receive various forms of federal funding directly and indirectly via federal programs, including but not limited to those governed by the Centers for Medicare and Medicaid Services through Medicaid and Medicare reimbursements and the Ryan White Comprehensive AIDS Resources Emergency Act of 1990. I may be, therefore, subject to the restrictions of HHS's Denial-of-Care Rule. These funds and related benefits account for a significant portion of my work and the healthcare services that I, and those that I supervise, provide to patients. Without such funding, we could not provide proper treatment to our patients, especially because a large portion of the population that we serve relies heavily on Medicaid and Medicare for its healthcare needs. I, therefore, have a reasonable fear that I could be sanctioned and lose federal funding for the work that I do as a result of nondiscrimination policies that I enforce in my department and amongst the staff that I supervise polices that are vital to providing proper care to my patients and other patients whose care I supervise. If such a loss of funding were to occur, it would result in service reductions if not closure of our programs in their entirety.
- 15. The "Denial-of-Care Rule" is inherently demeaning and codifies our government's belief that providers' freedoms are the most important and that patients are supplicants when they seek healthcare. This proposed rule is shameful.
- 16. As LA LGBT Center's Chief Medical Officer and Director of Clinical Research, my responsibility includes enforcing our nondiscrimination mandate with respect to all of our providers and staff, including those working on federally funded research. I, therefore, have a

## Case 5:19-cv-02916-NC Document 36-3 Filed 06/11/19 Page 7 of 7

reasonable fear that the ability to provide federally funded healthcare services and conduct federally funded research could be severely impeded potentially putting patients and research participants at risk. I could also be subject to sanctions as the principal investigator for many federally funded research programs at the LA LGBT Center. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Dated: June 4, 2019 Respectfully submitted, Robert Bolan, MD 

ll ll		
1 2 3 4 5 6 7 8 9 10 11	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200 Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS 199 Water Street, 22nd Floor New York, NY 10038 Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org  JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 105 West Adams, 26th Floor Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307 jgliksberg@lambdalegal.org	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837) MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL, COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl. San José, CA 95110-1770 Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org LEE H. RUBIN (SBN 141331) MAYER BROWN LLP Two Palo Alto Square, Suite 300 3000 El Camino Real Palo Alto, CA 94306-2112 Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com  Counsel for Plaintiffs
12		
13	UNITED STATES I	
1.5	NORTHERN DISTRIC	CT OF CALIFORNIA
14	COUNTY OF SANTA CLARA, TRUST	Case No. 5:19-cv-2916
15	WOMEN SEATTLE, LOS ANGELES LGBT	Case No. 3.19-60-2910
1.0	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH,	DECLARATION OF JULIE
16	BRADBURY-SULLIVAN LGBT	BURKHART IN SUPPORT OF PLAINTIFFS' MOTION FOR
17	COMMUNITY CENTER, CENTER ON	NATIONWIDE PRELIMINARY
18	HALSTED, HARTFORD GYN CENTER,	INJUNCTION
	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION	
19	OF LGBTQ+ PSYCHIATRISTS, AMERICAN	
20	ASSOCIATION OF PHYSICIANS FOR	
21	HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ	
	EQUALITY, COLLEEN MCNICHOLAS,	
22	ROBERT BOLAN, WARD CARPENTER,	
23	SARAH HENN, and RANDY PUMPHREY,	
24	Plaintiffs,	
25	vs.	
25	U.S. DEPARTMENT OF HEALTH AND	
26	HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF	
27	HEALTH AND HUMAN SERVICES,	
28	Defendants.	

I, Julie Burkhart, declare as follows:

- 1. I am the Founder and Chief Executive Officer of Trust Women, which operates clinics that provide full-spectrum reproductive healthcare and certain health services to the LGBTQ community. Trust Women operates clinics in Kansas, Oklahoma, and Washington State with the goal of ensuring affordable access to abortion, contraception, LGBTQ healthcare, and other reproductive healthcare services.
- 2. I submit this Declaration in support of Plaintiffs' challenge to the final rule promulgated by the Department of Health and Human Services ("HHS") relating to "Conscience Rights in Health Care" (the "Rule") and the Rule's enforcement by the HHS Office of Civil Rights ("OCR").
- 3. Trust Women Scattle, located in Seattle, Washington, opened in June 2017 and provides reproductive healthcare, including abortion services, contraceptive care, and general gynecological care, as well as a growing number of services for LGBTQ patients, including the provision of gender-confirmation hormone therapies. The clinic receives Medicaid funding.
- 4. Trust Women's mission is to operate clinics that empower our patients to make autonomous decisions about their healthcare in a compassionate and non-judgmental environment. It is essential to Trust Women's mission that patients be treated with dignity, empathy, and respect, given complete and accurate medical information, and be empowered to make decisions about their health and lives free from judgment or disruptions in their care. Given our structure and the interactions that most staff have with patients and the provision of care, we seek to ensure that all staff treat each patient with dignity and compassion and respect patient autonomy.
- 5. Trust Women Seattle endeavors to protect our patients from judgment also because we offer services that are stigmatized and under threat in the U.S. We have seen the harm prejudice and judgment impose on our patients, including in their ability to access needed

<sup>&</sup>lt;sup>1</sup> This term refers to lesbian, gay, bisexual, transgender, and queer/questioning people and other sexual and gender minority individuals.

9

12 13

14 15

17

16

18 19

20

21 22

23

24 25

26

27 28 healthcare. For example, many of our patients come to us after being turned away from another provider.

- 6. To that end, Trust Women Seattle has a "no turn away" policy. For each patient, the clinic staff work to utilize healthcare benefits fully and raise any additional money from donors and other funds, if necessary. This practice ensures that we see patients regardless of their ability to pay.
- 7. This policy is largely contingent on the continued availability of state Medicaid reimbursement. If the clinic did not receive this income, it would have to attempt to raise significantly more money from contributors and other sources, which is not presently available. and extremely unlikely to be secured solely through these sources.
- 8. In 2018, approximately 64% of our abortion patients relied on Medicaid; approximately half of our patients receiving contraception relied on Medicaid; and approximately 60% of our income from providing transgender healthcare came from Medicaid.
- 9. Only 2 patients in the history of the clinic have been denied Medicaid coverage one due to residency ineligibility and the other due to income above the threshold. The clinic relies on Medicaid approvals to provide services.
- 10. I understand that Trust Women Seattle is considered a "subrecipient" under the Rule because it receives Medicaid funding through Washington State, which receives that funding as a direct recipient of HHS Medicaid funding.
- 11. I understand that the Rule states that "any entity that carries out any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of [HHS]," is prohibited from "requir[ing]" any "individual to perform or assist in the performance of any part of a health service program or research activity if such performance or assistance would be contrary to the individual's religious beliefs or moral convictions."
- 12. I understand that an "entity that carries out any part of a health service program or research activity" funded through HHS includes subrecipients, like Trust Women Seattle, who receive Medicaid reimbursement through state programs under the Rule.

- administrative costs. First, in order to ensure compliance, the clinic would need to hire an attorney to review the Rule and our policies. The clinic must also maintain records of its compliance, although the Rule does not specify the form of these records. The Rule states that patient privacy is not grounds to refuse access to OCR when it seeks to inspect records. To the extent that the Rule allows OCR access to unredacted patient information and internal clinic records, it is extremely problematic. Our mission is to protect and empower our patients—opening patient records to inspectors who may be hostile to our mission is antithetical to our central purpose.
- understand can be initiated by HHS based on a complaint or even in the absence of a complaint. I understand that under the Rule, OCR must conduct an investigation "whenever a compliance review, report, complaint, or any other information found by OCR indicates a threatened, potential, or actual failure to comply with Federal healthcare conscience and associated anti-discrimination laws or [the Rule]." The Rule is silent as to whether HHS must inform the clinic of an investigation or follow any particular procedure with respect to these investigations or inspections. The Clinic must cooperate with these measures, although the Rule is also silent as to the specific requirements of such cooperation.
- provider. At Trust Women's Kansas clinic, for example, we are already subject to significant scrutiny. The Board of Healing Arts in Kansas subpoenas information from our clinic and inspects the clinic without notice. These actions are based on "complaints" that have invariably been baseless and inappropriate allegations. The Department of Sanitation has also preformed unannounced inspections. All of these inspections and the production of information and records require costly advice from local counsel and the commitment of extensive staff resources, which together divert funds and personnel from our primary mission. We are targeted for these burdensome actions simply because we provide abortion.

- 16. Across the country, independent family-planning and other specialized reproductive-healthcare clinics are singled out for excessively burdensome treatment at the local, state, and federal level. As another example, in Oklahoma, Trust Women applied for two types of licenses. The Department of Health sat on the applications for 12 months, and we ultimately needed legal counsel to help get the process moving. To the extent that the Rule will impose such burdens on all independent clinics at the federal level, it is unworkable.
- 17. I understand that if OCR finds a violation of the Rule, OCR may withdraw or even clawback our funding. I understand that under the Rule, Washington State's Medicaid program, as the direct recipient that provides our Medicaid dollars, also bears "primary responsibility" for Trust Women Scattle's compliance with the Rule and stands to lose its HHS funding should Trust Women fail to comply with the Rule, incentivizing the program to discontinue its commitment to funding reproductive healthcare and services to LGBTQ patients. I further understand that under the Rule, the conduct or activity of contractors is "attributable" to the state for the purposes of enforcement or liability under the Weldon Amendment, further disincentivizing continued funding to the clinic. These enforcement mechanisms could shutter our clinics.
- 18. The Rule is unworkable for Trust Women Seattle. To the extent that it would prevent us from continuing to operate our business, force us to change core policies, or incite staff to exercise a unilateral veto over patient access to information and care, it would be extremely harmful for both our patients and our reputation, would cause devastating harm to our business, and would undermine our mission.
- 19. Small medical practices like Trust Women Seattle are specialized. We hire staff with special skills to work in our clinic, including staff sensitive to the experiences of women seeking abortion, contraceptive, and services for LGBTQ patients and medical staff with experience in assisting with gynecological care. Many staff members who work at the clinic have a connection to abortion care, contraception, or LGBTQ services, even if it only involves scheduling or doing bookkeeping or other administrative tasks related to such services. Trust Women Seattle is a small business, and part of our business model is to cross-train clinical and some non-clinical staff to serve multiple roles, many of which touch on providing information

about, scheduling, or directly providing abortion, contraception, or transgender care. For example, some employees focus on recording compliance with medical standards, which includes monitoring the provision of abortion care and contraceptive care at the clinic. Others perform medication management, sanitize instruments, and clean operating rooms and laboratories that may be used for general gynecological exams one day, and the provision of contraception or hormone therapy the next.

- 20. Although these activities do not involve the direct provision of care, if an employee were to refuse to participate in precisely these types of services, it would force a change in staffing structure that would be extremely costly and unworkable for the clinic. Likewise, if any employee were to unilaterally turn away a patient away seeking information or services, it would compromise our ability to provide healthcare services to our patients—the crux of both our mission and business. To the extent that we would have to ensure that all employees were not opposed to a new service anytime we add any services to our practice, it would significantly compromise our ability to expand our services and our resources.
- 21. Trust Women Scattle also has an emergency policy requiring all office personnel to be familiar with transfer agreements in the case of an emergency. This policy requires that any staff member assist in an emergency transfer, even if only by calling ahead to the hospital. To the extent that the Rule would prevent us from continuing to enforce this policy, it would be unworkable.
- 22. Were the Rule to prevent the clinic from requiring that staff members interact with all patients without judgment, it would likewise be unworkable. To the extent that we would be prevented from requiring that front-facing employees like receptionists, who do not assist in procedures according to our present understanding, be compassionate and supportive of the independent decision-making of our patients, it would undermine both our business and inhibit our patients' access to healthcare.
- 23. Patients at Trust Women Seattle have conveyed that they have been disrespected and demeaned by other healthcare providers for making independent decisions about their healthcare, including past and present reproductive healthcare choices. Likewise, transgender

patients have thanked us for addressing them with their chosen identity because they have been to healthcare providers who have refused to use their chosen pronouns or name based on prejudice. Our core mission is to treat all patients with dignity and compassion and, above all, to respect the autonomous choices of our patients. This mission is our central focus because we understand that many of our patients, and many patients around the country, have been marginalized in seeking needed medical services.

- 24. If, contrary to our practice of empowering patients to make their own decisions, employees were to substitute their opinions about a patient's care for the patient's judgment—essentially exercising a unilateral veto over the patient's receipt of care or information—and the clinic was rendered powerless to protect our patients without risking total loss of funding, we would either be forced to abandon our core mission or close.
- 25. We are concerned that, for example, an employee who supports access to contraception might be opposed to abortion or to abortion after a certain stage in pregnancy. Alternatively, staff who support abortion access may be willing to serve patients seeking reproductive healthcare but be opposed to treating members of the transgender community. Personal opinions can fall on a spectrum, and we are particularly vulnerable because of the breadth of services we provide and the varied communities we serve. We would be in a particularly untenable position if someone comes to assert a refusal after they were hired and staffed.
- 26. Extreme anti-abortion or anti-LGBTQ activists also pose a significant threat to the clinic and our staff, a threat that may become more significant if the clinic is unable to exercise the necessary controls within the clinic to protect patients and patient care. Because of the intense opposition to abortion and the ongoing presence of protestors outside our clinic, we are keenly aware of security threats posed by those who radically oppose abortion. It would be extremely dangerous to our staff and patients to have anyone on staff who would pose such a threat, and, to the extent that the Rule renders us powerless to prevent it, we would be forced to either assume that risk or risk total loss of and even clawback of federal funding. Further, patients and their communities trust us to be a safe place for them to receive nonjudgmental care and information.

We would lose that trust and potentially sacrifice the safety of everyone in the clinic were we to compromise our mission in response to the Rule.

- 27. To the extent the Rule would require Trust Women to change our cross-training and staffing policies or abandon our emergency policies, it would be impossible for Trust Women to continue providing abortion, contraception, and LGBTQ care.
- 28. It is unlikely, if not impossible, for the clinic to qualify for enough alternative funding from non-Medicaid sources to survive. At present levels, we could not survive.
- 29. Whether we continue to operate while constraining our provision of abortion, contraception, or LGBTQ services, or instead close altogether, our patients will suffer. Many of our patients rely on us for abortion, contraception, and transgender care that they cannot access anywhere else.
- 30. Even if we could continue operating by, for example, incorporating another type of practice to supplement the clinic's income, we would have to lay off staff and sacrifice our core mission to provide reproductive healthcare and services to LGBTQ patients. Further, that could not be achieved without fundamentally altering our business model and finding a new location, hiring additional specialized staff and physicians, purchasing new equipment, and retaining specialized administrative support. In short, incorporating another practice to stay open would completely undermine the mission and purpose of our clinic.
- 31. If we do close, it will be very difficult to reopen. Opening any kind of medical practice is complicated. It requires licensing, finding appropriate space, new equipment, supplies, insurance, and credentialing. Reopening our Seattle clinic after a closure would likely cost in excess of \$2,000,000 and, in Seattle, only 7% of downtown real estate is available for rent at all.
- 32. The Rule thus creates an impossible choice—either fundamentally change the way we operate, potentially compromising our core mission to provide compassionate reproductive healthcare and care to the LGBTQ community, or risk the loss of all funding and closure.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

	Case 5:19-cv-02916-NC Document 36-4 Filed 06/11/19 Page 9 of 9
1	Dated: June 5, 2019  Respectfully subspirated,
2	
3	Affect
5	Trust Women
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25 26	
27	
28	
	- 8 - DECLARATION OF JULIE BURKHART ISO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
	DECLARATION OF JULIE BURKHART ISO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

1 2	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837)
3	Washington, DC 20005	MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055)
4	Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org	H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL, COUNTY OF SANTA CLARA
5	GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS	70 West Hedding Street, East Wing, 9th Fl.
6	199 Water Street, 22nd Floor New York, NY 10038	San José, CA 95110-1770 Tel: (408) 299-5900; Fax: (408) 292-7240
7	Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org	mary.hanna-weir@cco.sccgov.org LEE H. RUBIN (SBN 141331)
8	JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND	MAYER BROWN LLP Two Palo Alto Square, Suite 300
9	EDUCATION FUND, INC.	3000 El Camino Real Palo Alto, CA 94306-2112
10	105 West Adams, 26th Floor Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307	Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com
11	jgliksberg@lambdalegal.org	Counsel for Plaintiffs
12		
13	UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA	
14	COUNTY OF SANTA CLARA, TRUST	
		Case No. 5:19-cy-2016
15	WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC.	Case No. 5:19-cv-2916
15 16	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH,	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS'
	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON	DECLARATION OF BRUCE BUTLER
16	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19 20	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS,	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19 20 21	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19 20 21 22	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19 20 21 22 23	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY, Plaintiffs, vs.	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19 20 21 22 23 24	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY, Plaintiffs, vs.  U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II,	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
16 17 18 19 20 21 22 23 24 25	CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY, Plaintiffs, vs.  U.S. DEPARTMENT OF HEALTH AND	DECLARATION OF BRUCE BUTLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY

5

6

7 8

9 10

12

13

11

14

15

16

17

18 19

20

21 22

23

24 25

26 27

28

# I, Bruce Butler, declare:

- 1. I am a resident of the State of California. I submit this declaration in support of the County of Santa Clara's ("County"), and its co-plaintiffs', Motion for Preliminary Injunction. I have personal knowledge of the facts set forth in this declaration. If called as a witness, I could and would testify competently to the matters set forth herein.
- 2. I am the Chief Executive officer of Valley Health Plan. In this role I oversee all health plan operations. I have held this position since March of 2015. Prior to my current role at Valley Health Plan, I served as the Chief Strategy Officer for the University of California Office of the President, Division of Health Sciences and Services. I have served in health care for 35 vears.
- 3. Valley Health Plan is a health maintenance organization ("HMO") owned and operated by the County of Santa Clara since 1985. Our mission is to provide affordable healthcare to a wide spectrum of Santa Clara County residents and community members, and to improve the overall health and wellbeing of Santa Clara County and our members. As an HMO, Valley Health Plan offers a set of different healthcare coverage plans that give enrolled members access to a range of medical services from physicians and other healthcare providers with whom Valley Health Plan contracts. The health plan member, or the entity paying for the member's coverage, selects a plan and pays a predetermined fee in exchange for securing the member's access to a set of covered healthcare services, including access to a network of primary and specialty care providers, nationwide pharmacy locations, and in-state laboratory locations, as well as other health care providers for behavioral health, substance abuse, chiropractic, acupuncture, and related services. Many of our provider partners are primarily focused on safety-net populations and our partnership with them provides them with an alternate and steady stream of payments that can help enable their work with safety net populations.
- 4. We serve a variety of populations, and many of our members have their healthcare plans with us paid for in whole or in part by the federal government:
- <u>Commercial members</u>: For these members, an employer secures healthcare coverage through Valley Health Plan for its employees. Approximately 10,450 people

obtain healthcare through our commercial memberships, and many Santa Clara County employees receive healthcare coverage through this option.

- b. Medi-Cal: The Santa Clara Family Health Plan (Family Health Plan) is an independent Health Authority created by the County in 1996 that works with the State to provide coverage to Medi-Cal enrollees. The Family Health Plan delegates to Valley Health Plan the responsibility for connecting a large portion of its Medi-Cal enrollees to covered healthcare services. Thus, Valley Health Plan provides administrative services, including access to its extensive provider network, to the Family Health Plan's Medi-Cal enrollees. The Family Health Plan is compensated by the State for providing coverage, and the Family Health Plan in turn compensates Valley Health Plan for its services. Valley Health Plan's current enrollment of Medi-Cal Managed Care members is approximately 120,000. Were we to be disqualified from receiving federal funds passed through the Department of Health and Human Services we would no longer be able to offer services to the Medi-Cal Managed Care members.
- c. Covered California Health Exchange Program: Valley Health Plan is a Qualified Health Plan Issuer for Covered California, the California Health Benefit Exchange. Covered California is the state marketplace for health insurance, established following the enactment of the Patient Protection and Affordable Care Act (ACA). Under the ACA, each state is tasked with creating a marketplace for health insurance plans. The federal government subsidizes these plans for individuals who meet income-based eligibility requirement. Thus, through the Covered California marketplace, Valley Health Plan offers subsidized health insurance plans to eligible persons. There are approximately 15,000 members enrolled in Valley Health Plan through Covered California.
- d. **Family and Individual Plans:** Valley Health Plan offers an off-exchange product for individuals and families that allows those who don't qualify for subsidies to obtain insurance under the same terms as those offered through the Covered California exchange. There are a few hundred members enrolled in Valley Health Plan's direct family and individual plans.
- 5. When Valley Health Plan enters into a contract with a provider, Valley Health Plan requires that the provider inform us of the entire range of specific services they provide. A

sample of our standard provider agreement is attached as **Exhibit A**. We also require that a provider inform us if the scope of the services it offers is about to change or has changed. Exhibit A at 2.1(l). Without this information, we cannot match our members to providers who can appropriately care for them. For example, an obstetrician/gynecologist is required to list whether they provide abortion and sterilization care as part of the provider contract, and once that provider is part of the VHP network, the provider must provide those services or timely inform us that they no longer offer such services. *See* Exhibit A at 2.1(l). If providers were to not provide us with accurate information about the care they provide, it could delay or bar members from receiving the healthcare to which they are entitled.

- 6. We require each provider to sign a nondiscrimination provision stating that it "will not differentiate or discriminate in its provision of Covered Services to Members hereunder, because of race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, age or use of medical services, and . . . will render Covered Services to Members in the same manner, in accordance with the same standards, and within the same time availability as offered to other Clinic patients." Exhibit A at 2.1(k). Were our providers allowed to refuse to provide care to specific members on the basis of a member's identity or a connection between a member's identity and the care they were seeking, it would obstruct members' access to healthcare to which they are entitled, undercut our relationship with our members, and endanger member health. We strive to run an inclusive organization, and without the ability to enforce this policy, we would not be able to ensure access to healthcare services.
- 7. When a member is seeking healthcare services they call Member Services to be connected with a provider who can meet their needs. If one of our representatives responsible for answering calls through Member Services objected to connecting a member with care on the basis of the representative's cultural values, ethics, or religious beliefs, this could delay or bar a member's access to the healthcare to which they are entitled. For example, if a Member Services representative told a member that they could not connect them with services—without noting that this was because of the representative's own provider's cultural values, ethics, or religious beliefs—then that member might be left with the impression that Valley Health Plan would not

10 11

12

13 14

15 16

17

18

19

20

21

22 23

24

25

26

27 28 cover the service the member was seeking. And, while a limited subset of calls are recorded, Valley Health Plan would largely be left entirely unaware that a member sought certain care and was turned away be a Member Services representative.

8. Further, a Valley Health Plan nurse or doctor must review and approve a request for services before a member can obtain certain services. Valley Health Plan's medical management follows national clinical guidelines for determining medical necessity and whether to approve a specific clinical service. It would undermine our review system if a reviewing nurse or doctor—based on their own cultural values, ethics, or religious beliefs—rejected or ignored a request for service that should have been approved under Valley Health Plan's guidelines, particularly if they did so without informing anyone that the denial or non-action was due to their cultural values, ethics, or religious beliefs. Indeed, if the member did not appeal the ruling, Valley Health Plan might never learn that a nurse or doctor had rejected the request based on their cultural values, ethics, or religious beliefs. And as a result, that member might never get the medically indicated care to which they were entitled.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this Declaration was executed on June 5, 2019 in San José, California.

Respectfully submitted,

# **EXHIBIT A**

# PROVIDER AGREEMENT BY AND BETWEEN THE COUNTY OF SANTA CLARA, dba VALLEY HEALTH PLAN AND PROVIDER\_CONTRACT\_NAME

This agreement, effective as of **Effective\_Date** ("Effective Date"), is made and entered into by and between **Provider\_Contract\_Name** ("Provider"), and the County of Santa Clara, a subdivision of the state of California, ("County") doing business as Valley Health Plan ("VHP") for **Type\_of\_Services** ("Agreement"). Provider and Plan may be referred to individually as "Party" and collectively as "Parties".

# **RECITALS**

WHEREAS, County operates VHP ("Plan"), a Health Care Service Plan licensed pursuant to the Knox-Keene Health Care Service Act of 1975, as amended ("Knox-Keene Act");

WHEREAS; VHP arranges for the provision of Covered Services to Members (as hereinafter defined) of Plan;

WHEREAS, such Members may from time to time require the services of a health care Provider, or services at a location, which County is unable to provide, and Plan wishes to insure the provision of such services to Members;

WHEREAS, **Provider\_Contract\_Name** is a health care Provider duly licensed by the State of California to provide the services under this Agreement and Provider has the authority, applicable knowledge, and expertise to provide **Type\_of\_Services** at Provider's medical offices located at **«Address»**, **«City»**, **«State» «Zip»**.

#### **AGREEMENT**

NOW, THEREFORE, in consideration of the promises and the mutual covenants herein stated, and for the good and valuable consideration, the receipt and sufficiency of which are acknowledged, the parties agree as follows:

#### **ARTICLE I**

# **DEFINITIONS**

In addition to the definitions elsewhere in this Agreement, the following capitalized terms shall have the meanings set forth below:

1.1 "Accrediting Agency" means a nationally recognized agency invested in the assurance of quality care to patients, which helps organizations meet regulatory requirements, as well as, distinguish themselves from non-accredited competition. An Accrediting Agency (i) completes initial and periodic assessments of an organization, (ii) evaluates against a defined set of standards, and (iii) determines and issues an official

recognition of accreditation to organizations meeting those set standards. VHP's Accrediting Agency(s) are identified on the Valley Health Plan's website at www.valleyhealthplan.org.

- 1.2 "Applicable Requirements" means, to the extent applicable to the terms and conditions of this Agreement and the duties, rights and privileges hereunder, the requirements set forth in: (i) the Provider Manual, the VHP Language Assistance Program, and any other policies and procedures of VHP including the Quality Management Programs; (ii) federal and state laws and regulations and any amendments or updates thereto, including the Knox-Keene Act; (iii) the applicable Evidence of Coverage; (iv) Medicare and Medi-Cal laws and regulations or Centers for Medicare and Medicaid Services (CMS) and the Department of Health Care Services (DHCS) instructions and reporting requirements, including certification requirements; (v) the California Department of Managed Health Care (DMHC); (vi) the California Health Benefit Exchange; and (vii) VHP's Accrediting Agency standards.
- **1.3** "Authorization" means the written approval by Plan, to be obtained by a Provider, making a Referral or providing certain Covered Services (other than Emergency Services) to any Member, in accordance with Applicable Requirements. Covered Services approved by Plan, as applicable, in accordance with the foregoing are "Authorized".
- **1.4** "Clean Claim" means a billing form (e.g. UB-04, CMS 1500, or any subsequent form issued by CMS, or applicable electronic claim) submitted by Provider to VHP that (i) identifies the Member; (ii) identifies the items and services with codes listed in this Agreement, including Exhibits, or, if not specifically listed, identifies the items and services provided utilizing codes published in the Current Procedural Terminology ("CPT"), Healthcare Common Procedure Coding System ("HCPCS"), or other industry-standard codes utilized by Provider; (iii) if applicable, contains or attaches a required authorization or form as specified in this Agreement, and (iv) follows all industry standard clean claim practices.
- **1.5 "Contracted Services"** Covered Services that are within Provider's scope of practice provided to a Member pursuant to the Evidence of Coverage in effect at the time services are rendered and compensated in accordance with this Agreement.
- 1.6 "Coordination of Benefits" ("COB") means the determination of order of financial responsibility that will apply when two (2) or more payors provide coverage of services for an individual Member. When the primary and secondary benefits are coordinated, determination of financial responsibility shall be in accordance with Applicable Requirements.
- 1.7 "Co-payment" means the amount due from Member for Covered Services that is in accordance with Applicable Requirements and is disclosed and provided for in the Member's Evidence of Coverage. The reference to "Co-payments" may include copayments, deductibles, and co-insurance charges or other Member payment responsibility, and may be a fixed amount or a percentage of applicable payment for Covered Services rendered to the Member.

- 1.8 "Covered California" shall mean Covered California, California Health Benefit Exchange, the independent entity established within the government of the State of California and authorized under the Federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the Federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152) (collectively, "Affordable Care Act"), and the California Patient Protection and Affordable Care Act, (Chapter 655, Statutes of 2010) and Chapter 659, Statutes of 2010) ("California Affordable Care Act") to selectively contract with health insurance issuers in order to make available to enrollees of the exchange health care coverage choices available to qualified individuals, employers and employees.
- 1.9 "Covered Services" means all of the health care services and supplies: (i) that are Medically Necessary; (ii) that are generally available from provider; (iii) that provider is licensed to provide to Members; and (iv) that are covered under the terms of the Member's Evidence of Coverage at the time service is rendered. Plan shall retain the right and sole responsibility to determine whether a service is a Covered Service.
- **1.10** "Emergency Medical Condition" as set forth in Title 22, California Code of Regulations ("CCR"), section 51056, and California Health and Safety Code section 1317.1, means those services required for alleviation of a medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following:
  - (a) Placing the patient's health (or in the case of a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
    - **(b)** Serious impairment to bodily functions; or
    - **(c)** Serious dysfunction of any bodily organ or part.
- **1.11** "Emergency Services" means those medical and psychiatric services required that are (i) furnished by a physician qualified to furnish emergency services; and (ii) needed to evaluate or stabilize an Emergency Medical Condition.
- 1.12 "Evidence of Coverage" ("EOC") means the Plan handbook issued to a Member that describes coverage and benefits known as the Combined Evidence of Coverage and Disclosure Form as may be amended, modified, replaced, or supplemented from time to time and issued to Members by Plan pursuant to Title 28 of the California Code of Regulations § 1300.63.2.
- 1.13 "Language Assistance Program" means the language assistance program established by VHP in compliance with the requirements of the Health Care Language Assistance Act, pursuant to Health and Safety Code Section 1367.04 et seq. and California Code of Regulations ("CCR") 28 CCR 1300.67.04 et seq.
- 1.14 "Medically Necessary" means reasonable and necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness or injury as determined by a Physician, or, as appropriate, by another Provider under supervision of a Physician, in accordance with accepted medical and surgical practices and standards prevailing at the

time of treatment and in conformity with the professional and technical standards adopted by VHP, as applicable.

- **1.15** "Member" means each VHP Employer Group, Covered California, Individual and Family Plan, Medi-Cal, Healthy Kids enrollee or other individual included in the products reflected in the exhibits attached to and incorporated by reference to this Agreement.
- **1.16** "Physician(s)" means each duly licensed and qualified physician who has satisfied Plan's credentialing criteria and is under contract, directly or indirectly, with Plan to provide specified Covered Services to Members.
- **1.17** "Practitioner(s)" mean the other health care Providers that have entered or will enter into a written agreement, directly or indirectly, with Plan to provide certain Covered Services in return for a negotiated rate of compensation.
- 1.18 "Provider(s)" means the hospitals, community clinics, primary care and specialty care physicians, skilled nursing facilities, home health agencies, and other health care providers (including institutional, ancillary, behavioral health, and participating Physicians) that have entered or will enter into a written agreement, directly or indirectly, with Plan to provide certain Covered Services in return for a negotiated rate of compensation.
- 1.19 "Primary Care Physician(s)" ("PCP") means the Physician responsible for supervising, coordinating, and providing initial and primary care to each Member who selects or is assigned to such physician. The PCP is responsible for: managing the delivery of all health and medical care services; for initial referrals for specialist care; and for maintaining the continuity of patient care to such Members. PCP includes physicians practicing in the area of internal medicine, general and family practice, or pediatrics; and may also include physicians in other areas of practice, as applicable, to the extent permitted by VHP and Applicable Requirements.
- **1.20** "Provider Manual" means, collectively, VHP's standards, protocols, policies and procedures, guidelines, manuals, and related written materials. The Provider Manual(s) are incorporated into this Agreement and may be revised or replaced from time to time, in accordance with the terms of this Agreement. The Provider Manual can be located on Valley Health Plan's website at <a href="www.valleyhealthplan.org">www.valleyhealthplan.org</a>. If any provisions in the Provider Manual or any amendments thereto are inconsistent with the terms of this Agreement, the terms of this Agreement shall prevail.
- **1.21** "QHP Contract" shall mean the Qualified Health Plan contract between Plan and Covered California through which Plan is authorized to enroll individuals as Covered California Members.
- **1.22** "Quality Management Programs" shall include both Quality Improvement and Utilization Management Programs and means VHP policies, procedures, protocols and functions designed to monitor and ensure the quality and appropriate utilization of Covered Services provided to Members. The Quality Management Programs are described in the Provider Manual.

- 1.23 "Santa Clara Family Health Plan" ("SCFHP") means the health care service plan licensed pursuant to the Knox-Keene Act and governed by the Santa Clara County Health Authority.
- **1.24** "Surcharge" means an additional fee that is charged to a Member for Covered Services, which is not permitted under applicable legal requirements, and is neither disclosed nor provided for in the Member's Evidence of Coverage.

#### **ARTICLE II**

# **PROVIDER OBLIGATIONS**

#### 2.1 Services.

- (a) Provider will provide the **Type\_of\_Services** services ("Contracted Services") to Members included in the product(s) identified in the exhibits attached to and incorporated by reference to this Agreement.
- **(b)** The Provider(s) must submit an application and be approved pursuant to all applicable credentialing procedures, before he or she may provide medical services pursuant to this Agreement.
- (c) Provider will maintain a current list of its Providers who are eligible in accordance with Section 2.9 of this Agreement, to provide medical services hereunder. Provider shall provide an updated list of any changes monthly.
- **(d)** Provider agrees to follow treatment guidelines equivalent to those required by the state in which Provider renders services or as outlined by Provider's specialty.
- **(e)** Providers will accept, diagnose, and treat those Members referred to Provider by Plan in accordance with the terms of this Agreement and consistent with accepted principles of medical practice and ethics.
- **(f)** Except for Emergency Services as defined herein and unless otherwise authorized, Provider will make best efforts to use Physicians and a contracted Providers for those Members requiring additional professional and Covered Services.
- (g) Subject to other provisions in this Agreement, the Provider will determine the method, details, and means of performing Contracted Services pursuant to this Agreement. Provider acknowledges that all VHP's decisions, policies and procedures regarding the provision of Covered Services to Members apply solely to Provider's rights to compensation, and will not be construed as interference with, or direction or substitution of, Provider's due diligence and judgment in the provision of Covered Services.

- (h) Provider will maintain adequate personnel and facilities to meet its responsibilities under this Agreement. Provider will supervise all personnel employed by it. Provider's personnel, equipment and facilities will be licensed or certified to the extent required by law. Plan or its designee(s), the DHCS, the DMHC or other regulatory agencies may conduct periodic site visits to assess the adequacy of personnel and facilities maintained by Provider. If any of the personnel and/or facilities maintained at any site is found to be inadequate, Plan must be notified, and Provider must develop and implement a plan of correction in accordance with Plan's Quality Management Programs and applicable state and federal laws.
- (i) Provider will be responsible, at its sole cost and expense, for providing licensed persons or technicians to assist in the performance of Contracted Services hereunder.
- (j) Provider will comply with Plan's drug formularies and treatment protocols, subject to generally accepted medical practice standards. Provider will comply with Title 22, CCR, section 53214, and with DHCS standards for the appropriate use, storage and handling of pharmaceutical items.
- **(k)** Provider will not differentiate or discriminate in its provision of Contracted Services to Members hereunder, because of race, color, national origin, ancestry, religion, sex, marital status, sexual orientation, age or use of medical services, and Provider will render services to Members in the same manner, in accordance with the same standards, and within the same time availability as offered to Provider's other patients.
- (I) Provider will notify the Plan of a pending or actual change in scope of service available, or any other factors which might materially affect the Provider's ability to provide services and carry out all other provisions under this Agreement.
- (m) Provider agrees to comply with Plan's Language Assistance Program Requirements as outlined in **Exhibit F** that is attached to and incorporated herein by this reference and any other Applicable Requirements.
- (n) Provider agrees to comply with Plan's Timely Access Standards as outlined in **Exhibit G** that is attached to and incorporated herein by this reference.
- **(o)** Provider agrees to comply with the Covered California Requirements as specified in **Exhibit H** that is attached to and incorporated herein by this reference.
- **2.2 Continuity of Care.** The completion of Covered Services shall be provided by a terminated Provider to a Member who at the time of the contract's termination was receiving services from that Provider as required by law.
- **2.3 Standard of Care.** Provider shall ensure that Covered Services furnished by Provider to Member are (i) Medically Necessary; (ii) provided in accordance with the standard of care prevailing within the medical community at the time of treatment; (iii)

provided in coordination with appropriate health prevention and education measures; and (iv) in consultation with Plan.

- **Improvement Programs.** Provider shall establish and maintain quality improvement and utilization management programs to monitor the quality and utilization of Covered Services rendered to members within and across the healthcare organization. settings, and all levels of care. Provider shall fully cooperate with and participate in Plan's Quality Improvement (QI) and Utilization Management (UM) Programs, as applicable. Provider will operate a QI program that is compliant and responsive to public health initiatives, federal, state, and local regulators and accreditation bodies. Provider's QI program shall include a system for monitoring and evaluating accessibility of care. Provider shall support the Plan's ongoing efforts to improve clinical care and services through activities including, but not limited to safe clinical practices, assessment and improvement of clinical care as necessary, measuring quality of services and member experience, and efficient utilization of resources. Provider agrees to implement any reasonable change required by Plan regarding any Provider or problem identified by Plan's Quality Improvement and/or Utilization Management Programs. Provider shall permit Plan personnel to review medical records of Members and Provider shall furnish copies of such pertinent sections of Members' medical records, as may be required, consistent with applicable confidentiality requirements as set forth in this Agreement. Provider agrees to provide to Plan, monthly, all Member data necessary for Plan to maintain and operate its QI and UM Programs and comply with all encounter data submission requirements imposed by Plan and/or any government regulatory agency.
  - (a) Provider shall designate experienced Utilization Management staff, capable of effectively coordinating the provision of Covered Services to Members. The UM staff shall, among other duties, assist Provider and Plan with respect to implementing Covered Service authorizations, approval of Member referrals, and such other duties as Provider shall designate from time to time. Prior authorization is required for all Covered Services except as determined by DMHC policy. Contacts for prior authorization of Covered Services are referenced in **Exhibit D** which is attached to and incorporated herein by this reference.
  - (b) Provider shall fully comply with Plan's Quality Management Programs and with any changes thereto. Upon request, Provider agrees to furnish Plan with Provider's performance data for quality improvement activities including compiling and comparing the performance data for display to our Members in order for Plan to meet their regulatory or accreditation requirements. Information requested must be readily available and requested within a reasonable time frame.
  - (c) Provider shall cooperate with Plan and/or any external peer review organization in the conduct of QI functions and in solving problems which includes potential quality issues. Provider shall provide Plan with information and reports as are reasonably necessary for Plan to conduct, or, if applicable, monitor Provider's delegated conduct of quality improvement functions. Provider shall also provide Plan with information and reports as are necessary for Plan to maintain compliance with DMHC, CMS, Covered California and Accrediting Agency requirements and/or state and federal law.

- 2.5 Member Transfer or Termination. Provider shall not ask Plan to terminate a Member or transfer a Member to another Provider because of a Member's medical condition or need for, or utilization of Covered Services. However, Plan and Provider may determine that the transfer of certain Members to another Provider may be Medically Necessary. Such determination shall be based on the following: (i) the Member's medical condition; (ii) the standard of care prevailing within the applicable medical community at the time of treatment; (iii) Provider's clinical capabilities, expertise and resources regarding the medical condition and standard of care under review; and (iv) the clinical capabilities, expertise and resources of another Provider under consideration to assume the care of such Member.
- **2.6 Eligibility Verification**. Provider shall obtain from Plan verification of the eligibility of all Members who receive Covered Services pursuant to this Agreement. If eligibility verification is not possible prior to the provision of Covered Services, Provider shall request such verification at the earliest possible opportunity thereafter, prior to billing Plan; provided, however, that Provider shall not be required to obtain Plan's approval prior to rendering Emergency Services to Members. Plan agrees to provide access to eligibility verification twenty-four (24) hours per day, seven (7) days per week. If Provider fails to verify eligibility which results in Provider rendering services to ineligible patients, Plan shall have no financial responsibility to reimburse Provider for any such services rendered to such ineligible patients.
- **2.7 Authorization Requirements.** Provider agrees to comply with VHP's authorization procedures and shall obtain prior authorization from Plan for all Covered Services, as required herein and in the Provider Manual. Additionally, Provider agrees to obtain prior authorization from Plan before providing any item or service not included in the original referral. If prior approval for additional items or services is not obtained, payment for services will be denied. Plan's contacts for prior authorization are set forth in **Exhibit D** to this Agreement.
  - (a) Upon request, Provider must promptly provide Plan with all information and documentation to enable Plan to determine whether to authorize services. Provider agrees to comply with the prior authorization process as set forth in the Provider Manual, and as required by Plan's Utilization Management Department.
  - **(b)** Provider will provide a report to referring physician within three (3) working days, unless a significant finding warrants immediate reporting.
  - **(c)** Provider acknowledges that nothing in this contract should be constructed to prevent Provider from freely communicating with patients about treatment options, including medication treatment options, regardless of benefit coverage limitations.
- 2.8 Member Grievances. Provider shall cooperate with Plan in resolving Member grievances related to the provision of Covered Services in accordance with Plan's Grievance and Appeals Procedures. Provider agrees to make available to Members copies of Plan's Grievance and Appeals Procedures and shall notify Plan within forty-eight (48) hours of the time it becomes aware of any Member grievances. Provider shall investigate all

Member grievances within the time frames specified by Plan and use its best efforts to assist Plan in resolving grievances in a fair and equitable manner.

# 2.9 Credentialing; Quality Assessment/Improvement; Grievance

- (a) Provider must submit an application to Plan in accordance with Plan's credentialing procedures and must provide Plan with any requested information, records, summaries of records and statistical reports specific to Provider including, but not limited to, utilization profiles pertinent to Provider's provision of medical services, professional qualifications, licensing and credentialing information. Provider will not be permitted to provide services to Plan members until they have been notified by Plan that their Credentialing Process is complete and has been approved. Provider will execute any releases requested by Plan to permit credentialing, recredentialing, discipline, utilization management, and quality assessment and improvement determinations to be made with respect to Provider. Provider must provide such information for all location(s) and/or individual Provider(s) containing the information set forth in **Exhibit C** of this document, which is attached hereto and incorporated herein by reference. Provider will cooperate and assist with site visits required for regulatory, quality assessment or credentialing purposes.
- **(b)** Provider agrees to be bound by and shall fully comply with all Applicable Requirements. Provider shall review the Provider Manual including Plan's Quality Management Programs prior to or promptly following the execution of this Agreement. Provider shall fully comply and cooperate with Plan's Provider Manual requirements including the Quality Management Programs and with any subsequent changes thereto.
- (c) Prior to execution of this Agreement and thirty (30) days prior to implementing any change, Provider must provide Plan with the information described in **Exhibit C**, including a list of Providers licensed and/or credentialed employees, Provider sites, addresses and operating hours. Provider will maintain a current list of its Providers who are eligible to provide medical services hereunder. Provider shall provide an updated list specifying any changes of Providers to Plan monthly.
- (d) The Parties acknowledge and agree that Plan or another contracting health plan committee that reviews the quality of medical services rendered to Members will act in the capacity of a "peer review committee" for purposes of applicable law. For purposes of this section, "quality of medical services" includes, without limitation, matters involving utilization management and compliance with requirements, rules or regulations relating to the delivery, cost, quality or appropriateness of medical care provided to Members. Except as otherwise provided by law, the immunities and protections provided to peer review committees under applicable provisions of the California Civil, Evidence and Health and Safety Codes will apply to any such committee when performing the function described herein.
- **(e)** Provider acknowledges that Plan is accredited. Provider's performance under this Agreement must comply with applicable Plan and Accrediting Agency standards. Provider certifies that personnel who are to provide

services to Plan Members maintain appropriate skills, competency, and continuing education commensurate with their current job descriptions. Upon request, Provider will provide Plan with documentation evidencing that the aforementioned standards have been met. Further, Provider agrees to cooperate with and/or participate in any Accrediting Agency review or survey as requested by the Plan and/or Accrediting Agency.

- **(f)** Under Plan's direction, Provider agrees to cooperate in the resolution of all Member medical disputes in accordance with the procedures of, and within the timeframes designated by Plan in its Provider Manual.
- **(g)** Provider acknowledges that Plan has independent obligations with respect to quality management under the Knox-Keene Act. Plan shall be responsible for developing and operating a quality assurance and improvement program in connection with Covered Services.
- (h) Provider shall fully comply with Plan's Quality Management Programs and with any changes thereto. Upon request, Provider agrees to furnish Plan with Provider's performance data for quality improvement activities including compiling and comparing the performance data for display to our Members in order for Plan to meet regulatory or accreditation requirements. Information requested must be readily available and requested within a reasonable time frame.
- Reporting Requirements. Provider agrees to provide and timely submit to Plan all reports as may be required under this Agreement and/or by federal, state, and local standard regulations and accreditation bodies. Provider agrees to support and promote Plan's Quality Improvement Programs to sustain and/or improve quality of care, safety, efficiency, and continuity and coordination of services, including behavioral health services when applicable. Provider agrees to maintain a systematic process to continuously identify, measure, assess, monitor and improve the quality, safety, and efficiency of clinical care, and quality of service. Provider reports must reveal trends or patterns and identified opportunities for improvement that are based on current scientific knowledge, and evidencebased clinical practice guidelines recognized in the industry. Provider reports must be structured to produce statistically valid performance measures for care and services rendered. Provider shall exercise ongoing efforts supported by concrete data or evidence(s) to improve structural and organizational performance measures. Provider agrees to re-evaluate and determine the effectiveness of measures implemented based on significant statistical findings against organizational goals or benchmarks set. Provider agrees to establish collaborative partnerships with the Plan to implement interventions or service needs of the Plan's Members throughout the entire continuum of care to improve and achieve desired health outcomes. The Plan has the duty to conduct UM, QI, and fraud prevention detection activities in accordance with Plan policies, federal, state, and local regulations, unless Plan delegated those duties. Provider shall cooperate with Plan in the conduct and oversight of those functions and provide Plan with information as is reasonably necessary for Plan to perform its functions.

# **ARTICLE III**

# **PLAN OBLIGATIONS**

- **3.1 Plan Operations.** Plan agrees to conduct the day-to-day administrative operations of a health care service plan for which it is responsible under state and federal law
- **3.2 Compensation.** Plan shall pay Provider for Contracted Services provided to Members as set forth in Article IV of this Agreement at the rates agreed to in **Exhibits A-1**, **A-2**, **A-3**, **A-4**, **A-5** and **A-6**, Compensation Schedules, attached to and incorporated herein by this reference, less Co-payments, as applicable.
- **3.3** Quality and Utilization of Covered Services. Plan shall monitor the quality and utilization of Covered Services provided to Members in accordance with the policies and procedures of Plan's Quality Improvement Programs and Utilization Review Programs established by Plan. Plan shall monitor and evaluate accessibility of care and address problems that develop. Plan shall review, at least annually, Provider's compliance with standards established by Plan.
  - (a) Quality Reviews. The Parties acknowledge and agree that Plan reviews the quality of medical services rendered to Members and shall act in the capacity of a "peer review committee" for purposes of Applicable Requirements. For purposes of this section, "quality of medical services" includes, without limitation, matters involving utilization management and compliance with requirements, rules or regulations relating to the delivery, cost, quality or appropriateness of medical care provided to Members. Except as otherwise provided by law, the immunities and protections provided to peer review committees under applicable provisions of the California Civil, Evidence, and Health and Safety Codes will apply to any such committee when performing the function described herein.

# (b) Quality Improvement Services.

- i. Plan shall perform quality improvement services.
- ii. Plan shall establish a Quality Improvement (QI) Plan and apply criteria and methodologies to review and measure the quality of professional, ancillary and inpatient professional services.
- iii. Plan shall conduct, or require a designee to conduct, meetings at least quarterly, pursuant to a set agenda, to review and measure the quality of health care services provided or arranged by Provider or its subcontractors.
- iv. Plan shall on a periodic basis, conduct clinical quality improvement evaluations of the care rendered to members, to comply with DMHC requirements, Applicable Requirements and/or Plan policies.
- **3.4 Provider Manual(s).** VHP Provider Manual can be located at <a href="www.valleyhealthplan.org">www.valleyhealthplan.org</a>. Plan shall make available to Provider a Provider Manual(s) which shall include all administrative policies and procedures of Plan. Plan shall provide forty-five (45) business days' prior written notice to Provider of any amendments to the Provider Manual(s). Such amendments shall become effective upon expiration of the forty-five (45)

business day notice period unless Provider determines that such amendment adversely affects a material duty or responsibility of Provider and/or has detrimental economic effect upon Provider and Provider provides Plan with written notice of such determination within forty-five (45) business days of receiving notice of the applicable amendment from Plan. Plan and Provider shall attempt to agree to a written amendment to the Agreement which addresses the adverse effects of the amendment on Provider. If such an agreement cannot be reached by Provider and Plan, the amendment shall not be effective and shall have no force or effect on Provider and Provider shall have a right to terminate the Agreement in accordance with California Health and Safety Code Section 1375.7(b) prior to the implementation of the amendment.

#### **ARTICLE IV**

# COMPENSATION

**4.1 Billing.** Provider shall submit Clean Claims to Plan for all Contracted Services rendered to a Member, within the timeframes established in **Exhibits A-1**, **A-2**, **A-3**, **A-4**, **A-5** and **A-6**, attached to and incorporated herein by this reference.

# 4.2 Payment.

- (a) Plan agrees to pay Provider for Medically Necessary Covered Services provided to Members at the rates set forth in **Exhibit A-1**, **A-2**, **A-3**, **A-4**, **A-5 and A-6** of this Agreement minus the Member's Co-payment. Plan will pay Provider for Covered Services rendered to Member within forty-five (45) business days of receipt of Provider's undisputed, Clean Claim. A Clean Claim must include the information required by of this Agreement or in the Provider Manual available on the VHP website: <a href="https://www.valleyhealthplan.org">www.valleyhealthplan.org</a>.
- **(b)** Provider will be responsible for the collection of Coordination of Benefit payments for Members, and Plan will pay in accordance with Article 5 of this Agreement.
- **(c)** Balance Billing. Except for applicable Co-payment, Provider shall not invoice or balance bill Plan's Member for the difference between Provider's billed charges and the reimbursement paid by Plan for any Covered Service rendered.

# 4.3 Denying, Adjusting or Contesting a Claim and Reimbursement for the Overpayment of Clean Claims.

- (a) Denying, Adjusting or Contesting a Clean Claim. For each claim that is either denied, adjusted or contested, Plan shall provide an accurate and clear written explanation of the specific reasons for the action taken within the timeframes as specified in §1300.71(g) and (h) of the Department of Managed Health Care ("DMHC") Regulations.
- **(b)** Time for Contesting, Adjusting or Denying Claims. Plan may contest or deny a claim, or portion thereof, by notifying Provider in writing, that the claim is

contested or denied, within forty-five (45) working days after the date of receipt of the claim by Plan.

- (c) Reimbursement for Overpayment of Clean Claim. If Plan determines it has overpaid a Clean Claim, it shall notify Provider in writing through a separate Notice clearly identifying the claim, the name of the patient, date of service and including a clear explanation of the basis upon which Plan believes the amount paid on the claim was in excess of the amount due, including interest and penalties on the claim.
  - i. If Provider contests Plan's notice of reimbursement of the overpayment of a Clean Claim, Provider, within thirty (30) working days of the receipt of the notice of overpayment of a Clean Claim, shall send written Notice to Plan to state the basis upon which Provider believes that the Clean Claim was not overpaid. Plan shall receive and process the contested notice of overpayment of a Clean Claim as a dispute pursuant to this Agreement and applicable DMHC Regulations.
  - ii. If Provider does not contest Plan's notice of reimbursement of the overpayment of a Clean Claim, Provider shall reimburse Plan within thirty (30) working days of the receipt by Provider of the notice of overpayment of a Clean Claim.
  - iii. Plan may only offset an uncontested notice of reimbursement of the overpayment of a Clean Claim against Provider's current Clean Claim submission when: (i) Provider fails to reimburse Plan within the timeframe specified above; and (ii) this Agreement specifically authorizes Plan to offset an uncontested notice of overpayment of a Clean Claim from Provider's current Clean Claim submissions. If an overpayment of a Clean Claim(s) is offset against Provider's current Clean Claim(s) pursuant to this section, Plan shall provide a detailed written explanation to Provider, identifying the specific overpayment or overpayments that have been offset against the specific current Clean Claim(s).
- 4.4 Non-Covered Services. If Provider renders services to Members that are not Covered Services per the Member's EOC in effect at the time service is rendered, Provider may seek payment for such service(s) from the Member as allowed by law. Provider shall refrain from billing and/or collecting from a Member any charges in connection with services provided to the Member that are Non-Covered Services, unless Provider has first obtained a written acknowledgment of financial responsibility from the Member or the Member's legal representative. Such acknowledgement must be obtained in advance of rendering the Non-Covered Services.

#### **ARTICLE V**

# **COORDINATION OF BENEFITS/THIRD PARTY LIABILITY**

**5.1 Coordination of Benefits.** Certain claims for Contracted Services rendered to Members are claims for which another payor may be primarily or secondarily responsible

under Coordination of Benefit rules. For purposes of this Agreement, "Coordination of Benefits" or "COB" shall mean a method of sequentially assigning responsibility for the payment of Covered Services rendered to a Member among two (2) or more insurers or payors (e.g. Medicare). Plan and Provider shall cooperate to exchange information relating to Coordination of Benefits with regard to any Member for whom Provider has provided Contracted Services. In addition, Provider shall comply with the following requirements in such situations:

- (a) Plan as Primary Payor. When Plan is the primary payor, Provider shall accept the amount set forth in this Agreement as payment in full for Contracted Services from Plan. However, Provider shall have the right to collect Co-payments and payments for Non-Covered Services from Members and shall have the right to pursue and retain COB revenue from any secondary payor.
- **(b) Plan as Secondary Payor.** When Plan is the secondary payor, Provider shall promptly bill and take reasonable steps to collect payment from the primary payor. Plan shall pay Provider the difference between the amount collected from the primary payor and one hundred percent (100%) of the rates set forth in **Exhibit A-1, A-2, A-3, A-4, A-5 and A-6,** Compensation Schedules, of this Agreement.
- **5.2 Compliance with Law.** Notwithstanding any other provisions of this Agreement to the contrary, Provider shall, in all instances, collect from a Member, or from those who are financially responsible for such Member, the entire amount of such Member's Co-payment obligation(s) that are required to be collected in accordance with applicable state and federal laws.
- **5.3** Collection of Charges from Third-Parties. If a Member is entitled to payment from a third-party, Plan shall have no objection to Provider engaging in collection of any claims or demands against such third parties for amounts due for Contracted Services, so long as Provider gives Plan prior written notice of its intent to pursue such collection.
- **5.4 COB Obligations of Plan.** Plan shall provide COB information to Provider by supplying available data from the Member at the point of enrollment and supplying such data to Provider when available.
- **5.5** Assignment of Third-Party Liability Payments. If Provider collects any third-party liability payments for Contracted Services provided to a Member and has also previously received payments for such Contracted Services from Plan, Provider shall reimburse Plan the amount paid by Plan for said Member.

#### **ARTICLE VI**

# **COMPLIANCE WITH DMHC REGULATORY REQUIREMENTS**

**6.1 Records Maintenance.** Provider shall, with respect to services provided under this Agreement, cooperate fully with Plan by, among other things, maintaining and making available to Plan and the Director of the DMHC, all records necessary: (i) to ensure

continuity and quality of care for Members; (ii) to fulfill Plan's obligations under the Knox-Keene Act and implementing regulations; and (iii) for Plan to verify Provider's compliance with any of the terms and conditions of this Agreement. Provider shall maintain medical records, including without limitation their confidentiality as required under federal HIPAA law, and the Confidentiality of Medical Information Act, California Civil Code Section 56 et seq., in a manner consistent with the requirements of Applicable Requirements. Provider shall not allow unauthorized persons to view confidential records and shall have safeguards to prevent unauthorized viewing of confidential files. Provider agrees to maintain all books and records in a form in accordance with the general standards applicable to such books and records at Provider's place of business or at such other mutually agreeable location in California. Provider agrees to maintain all books and records provided for in this Section 6.1 for ten (10) years, or as may be otherwise required under Applicable Requirements, or CMS requirements, and such obligation shall not terminate upon termination of this Agreement, whether by rescission or otherwise.

- 6.2 Access to Records; Inspection. Plan shall have access, at all reasonable times upon reasonable demand, to the books, records and papers of Provider, (including but not limited to patient medical records,) relating to Covered Services provided to Members under this Agreement, to the cost thereof and to payments received by Provider from Members. Provider agrees to permit the DHCS, DMHC, the California Department of Public Health, or their authorized representatives, to conduct a site evaluation of Provider facilities and/or to inspect, examine or copy, at all reasonable times, upon reasonable demand, all such books and records described in this Section 6.2. Provider agrees to cooperate with all regulatory and governmental agencies in all aspects of the inspection process.
- **6.3 Knox-Keene Act.** Provider understands and acknowledges that Plan is subject to the provisions of the Knox-Keene Act (Chapter 2.2 of Division 2 of the Health and Safety Code) and implementing regulations (Chapter 1 of Division 1 of Title 28 of the California Code of Regulations) ("Regulations"). Any provision required to be in this Agreement by either of the above shall bind Plan whether or not provided in this Agreement. Provider shall comply with any and all Applicable Requirements imposed upon Plan and Provider under the Knox-Keene Act and Regulations.
- 6.4 **No Surcharges.** In no event, including but not limited to nonpayment by Provider or Plan, Provider's or Plan's insolvency or breach of this Agreement, shall any Member be liable for any sums owed to Provider by Plan, and Provider shall not bill, charge, collect a deposit or other sum or seek compensation, remuneration or reimbursement from, or maintain any action or have any recourse against, or make any Surcharge upon, a Member or other person acting on a Member's behalf. This provision shall not prohibit collection of Co-payments or COB revenues from secondary carriers by which the Member is covered. In the event Plan receives notice that a Member has been surcharged by Provider, Plan shall notify Provider in writing within ten (10) working days of the receipt of said notice and Plan shall take appropriate action. In the event Plan and Provider mutually determine, in writing, that Member has been Surcharged by Provider, Plan may refund the Surcharge to the Member and deduct the amount of such Surcharge from compensation due Provider pursuant to this Agreement. In the event there is a dispute regarding whether Provider has Surcharged a Member, Provider and Plan agree to meet to discuss said dispute no later than ten (10) calendar days following the receipt of a written request by the

other party. Should the Parties fail to mutually resolve said dispute, said dispute shall be submitted by the Parties to dispute resolution as provided in Section 10 of this Agreement within ten (10) calendar days following the aforedescribed meeting of the Parties. The obligations set forth in this Section 6.4 shall survive the termination of this Agreement regardless of the cause giving rise to such termination and shall be construed for the benefit of a Member, and the provisions of this Section 6.4 shall supersede any oral or written agreement to the contrary now existing or hereafter entered into between Provider and a Member or persons acting on behalf of either of them.

- **6.5** Language Assistance Program. Plan shall maintain an ongoing language assistance program to ensure Limited English Proficient ("LEP") Members have appropriate access to language assistance while accessing any health care service, pursuant to California Health and Safety Code §§ 1367(e)(3), 1367.04 and 1367.07 and California Insurance Code §§ 10133.8 and 10133.9. Provider shall make best efforts to cooperate and comply, with Plan's Language Assistance Program, which is outlined in **Exhibit F.**
- **6.6 Further Amendments.** Plan and Provider acknowledge that the DMHC may require that the parties further amend this Agreement to conform to the Knox-Keene Act. If the DMHC requires such further amendments, Plan shall notify Provider in writing of such amendments. Provider shall then have sixty (60) days from the date of Plan's notice to reject the proposed amendments by written notice to Plan. If Plan does not receive such written notice Plan has the option to terminate this Agreement upon sixty (60) days written notice.
- **6.7 Subcontractors.** Without limiting any provision in the Agreement regarding assignment and delegation, Provider agrees to maintain and make available for inspection by Plan and the DMHC, written copies of all contracts between Provider and any of its subcontractors.
- **6.8 Filing a Complaint.** Members of the Plan are entitled to the following information regarding the Department of Managed Health Care:
  - "The California Department of Managed Health Care is responsible for regulating health care service plans. If you have a grievance against your health plan, you should first telephone your health plan at 408-885-4760 or 1-888-421-8444 (toll-free) and use your health plan's Grievance process before contacting the Department. Utilizing this Grievance procedure does not prohibit any potential legal rights or remedies that may be available to you. If you need help with a grievance involving an emergency, a grievance that has not been satisfactorily resolved by your health plan, or a grievance that has remained unresolved for more than 30 days, you may call the department for assistance. You may also be eligible for an Independent Medical Review (IMR). If you are eligible for IMR, the IMR process will provide an impartial review of medical decisions made by a health plan related to the medical necessity of a proposed service or treatment, coverage decisions for treatments that are experimental or investigational in nature and payment disputes for emergency or urgent medical services. The department also has a toll-free telephone number (1-888-HMO-2219) and a TDD line (1-877-688-9891) for the hearing and speech impaired. The Department's Internet website

<u>www.hmohelp.ca.gov</u> has complaint forms, IMR application forms and instructions online."

# 6.9 Compliance.

- (a) Provider certifies that none of its employees or agents providing service under this Agreement (hereafter "Practitioners") have been convicted of a criminal offense related to health care, nor are any listed by any federal or state agency as debarred, excluded or otherwise ineligible for participation in Medicare, Medi-Cal, or any other federal or state funded health care program. Provider certifies that it has performed an appropriate screening of Providers prior to making this certification, that it will screen all new Providers, and that it will monitor the status of existing Providers. Provider certifies that they and their Practitioners possess all licenses required and those said licenses are in good standing. Provider certifies that in providing these Contracted Services, they and their Practitioners are operating within any and all limitations or restrictions of these licenses. Provider further certifies that none of its directors, managing employees, and owners of five percent interest, or more, in Provider's business have been convicted of any health care related offenses nor excluded from Medicare, Medi-Cal, or any other federal or state funded health care program.
- (b) Provider agrees to notify the Plan immediately should Provider or Practitioner be investigated, charged, or convicted of a health care related offense. During the pendency of any such proceedings, Provider or a Practitioner may, at the request of the Plan, be removed from any responsibility for, or involvement in, the provision of services under this Agreement. It is the Provider's obligation to keep the Plan fully informed about the status of such proceedings and to consult with the County prior to taking any action which will directly impact the County. This Agreement may be terminated immediately by Plan upon the actual exclusion, debarment, loss of licensure, or conviction of Provider or of a Provider of a health care offense.
- **(c)** Provider will indemnify, defend, and hold harmless Plan for any loss or damage resulting from the conviction, debarment, or exclusion of Provider, or Practitioners, or subcontractors.
- 6.10 Directory Requirements. Provider agrees to comply with Health and Safety Code Section 1367.27 et seq. Provider agrees to coordinate with VHP to verify and maintain all directory requirements in compliance with HSC § 1367.27. Said requirements shall include; (1) participation in a bi-annual audit to verify the Provider contact information and participating Provider profile(s) information is accurately represented in the VHP Provider Directory, (2) provide an affirmative response to the Provider Directory audit confirming the information represented is current and accurate, and (3) if information is inaccurate, provide VHP with current and accurate information. The Provider Directory audit process shall include a Provider notification informing Providers they have thirty (30) business days to provide VHP with their affirmative response. If a response is not received within 30 business days, VHP shall issue a final notice providing an additional ten (10) business days to receive Providers affirmative response. Provider acknowledges that non-responsive Providers are removed from the VHP Provider Directory until the directory

information is confirmed. Additionally, Provider agrees to timely notify VHP when either of the following occurs:

- (a) Provider agrees to inform the Plan within five (5) business days when the Provider is not accepting new patients.
- **(b)** Provider agrees to inform the Plan within five (5) business days when the Provider changes from not accepting new patients to accepting new patients.

#### **ARTICLE VII**

# MEDICAL RECORDS, HIPAA AND THE HITECH ACT

- **7.1 Medical Records.** Provider shall maintain for Members a single standard medical record, containing such accurate, descriptive and timely information and preserved for such time period(s) as required by the rules and regulations of the California Department of Public Health, and The Joint Commission or any other comparable accreditation organization. Unless otherwise specifically agreed by Provider, it is the understanding and agreement of the parties that the records described herein are deemed to meet all record keeping requirements required of Plan pursuant to Applicable Requirements.
- **7.2 Member Access to Medical Records.** Provider shall ensure that Members have access to their medical records in accordance with the Applicable Requirements of state and federal laws and regulations.
- 7.3 Right to Inspect Medical Records. The medical records described in Section 7.1 above shall be and remain the property of Provider and shall not be removed or transferred from Provider except in accordance with Applicable Requirements and general Provider policies. Plan, regulatory agencies with jurisdiction over Plan's business, and their designated representatives shall have the right to inspect, review, and make copies of such records upon request to facilitate Plan's obligation to conduct quality improvement, utilization monitoring, and peer review activities as required by the Provider Manual and Applicable Requirements.
- **7.4 Confidentiality.** Provider and Plan agree to maintain the confidentiality of information contained in the medical records of Members in accordance with Applicable Requirements. Medical records may be disseminated to authorized Plan Physicians or Plan representatives or Review Committees, to Plan itself, or to an appropriate Plan peer review, Quality Improvement or Utilization Management Committee or subcommittee identified by Plan, or as otherwise required by law. Provider shall require that all Providers to comply with Applicable Requirements regarding confidentiality and disclosure of mental health records, medical records and other health and Member information.
  - (a) Provider acknowledges and agrees that all information received from Plan in connection with patients referred to Provider by Plan under this Agreement, including, without limitation, the compensation provisions, Member lists, marketing materials, Quality Management Programs, Provider Manual, telephone numbers, manuals, records, policies and agreements, are proprietary information and trade secrets of Plan. Provider and the officers, employees and agents of Provider will

keep such information confidential, except to the extent that confidentiality may not be maintained as to any such information under Applicable Requirements. Provider will obtain written consent of Plan prior to dissemination of any marketing materials or materials promoting health and wellness activities or other information that refers to Plan.

- 7.5 Plan and Governmental Agency Access to Records. Provider shall cooperate and assist with Plan, agencies of the state and federal government and their designees in maintaining and providing medical, financial, administrative and other records of Members as shall be requested by Plan, or such agencies. Plan and such agencies shall have access at reasonable times upon demand to the books, records and papers of Provider and their Practitioners relating to services provided to Members, the quality, appropriateness, timeliness, cost thereof, and any payments received by Provider or their Practitioners for Covered Services provided to Members.
- 7.6 Compliance with HIPAA and the HITECH Act. The parties hereto agree to comply with all applicable requirements of the Health Insurance Portability and Accountability Act of 1966 ("HIPAA") and the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), including, but not limited to, the HIPAA Privacy and Security Rules. The parties further agree, if required by HIPAA, or any other Applicable Requirements, to enter into a Business Associate Agreement which complies with the requirements set forth in 45 C.F.R. Sections 164.301, 164.312,164.316, 164.504(e)(2)(i)-(iii) and 42 U.S.C. Sections 17931 and 17935(a).

# 7.7 Electronic Protected Health Information.

- (a) Safeguards. Provider shall implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of the Electronic Protected Health Information (as defined at 45 C.F.R. 160.103) that it creates, receives, maintains, or transmits on behalf of Plan as required by Subpart 'C' of Part 164 of Title 45 of the Code of Federal Regulations.
- **(b)** Agent and Subcontractors. Provider shall require any agent, including a subcontractor to whom Provider provides Electronic Protected Health Information, to implement reasonable and appropriate safeguards to protect such Electronic Protected Health Information.
- (c) Reporting of Unauthorized Use or Disclosure. Provider shall report to Plan any Security Incident (as defined at 45 C.F.R. 160.103) of which Provider becomes aware.
- (d) Availability of Records upon Termination. The obligations contained in this Article XIII shall survive termination of this Agreement.



**INSURANCE AND INDEMNITY** 

**8.1** Insurance and Indemnity Requirements. Provider will comply with the insurance and indemnity requirements set forth in **Exhibit E**, which is attached to and incorporated herein by this reference. It is understood and agreed that County is self-insured pursuant to the authority granted in California Government Code section 990.4, and that such self-insurance satisfies Plan's and the County's obligations hereunder.

# 8.2 Insurance Terms.

- (a) Each of the policies required by this Agreement shall provide that, prior to the cancellation, change or amendment thereof; the contracting party shall receive a minimum of thirty (30) days' prior written notice.
- (b) If the malpractice insurance coverage provided is "claims made," and either party changes carriers or terminates coverage on or after termination of this Agreement, that party shall purchase a policy of "prior acts" or "tail" coverage for a minimum term of five (5) years from the termination of the policy in effect immediately prior to such tail policy. Such "tail" coverage shall have the same policy limits as the primary malpractice insurance coverage required under this Agreement.
- **(c)** Either party shall provide the other with certificates evidencing such insurance coverages upon the execution of this Agreement or from time to time thereafter as may be requested.

#### **ARTICLE IX**

# **TERM AND TERMINATION**

- **9.1 Term of Agreement.** The term of this Agreement shall commence on the Effective Date and continue for a period of one (1) year ("Initial Term") and shall automatically renew thereafter for up to four (4) additional consecutive one-year terms, unless earlier terminated as provided herein. This Agreement shall supersede any Letters of Agreement and/or Payment Agreements that were executed by the Parties prior to the Effective Date of this Agreement. For services rendered on or after the Effective Date of this Agreement's terms shall control.
- **9.2 Termination without Cause.** This agreement may be terminated by the Plan without cause by giving sixty (60) days prior written notice to Provider.
- **9.3 Termination of Agreement with Cause.** Either Plan or Provider may terminate this Agreement for cause as set forth in this Section 9.3, subject to the notice requirement and cure period set forth herein.
  - (a) Cause for Termination of Agreement by Provider. The following shall constitute cause for termination of this Agreement by Provider:
    - i. **Failure to Maintain Insurance.** Plan fails to maintain adequate professional and general liability coverage required under this Agreement or to replace coverage that is cancelled or otherwise terminated;

- ii. **Insolvency of Plan.** A petition is filed to declare Plan bankrupt or for reorganization under the bankruptcy laws of the United States or a receiver is appointed over all or any portion of Plan's assets, and the insolvency is not cured within thirty (30) days after said event;
- iii. **Failure to Maintain Government Approvals.** Plan is unable to secure and maintain in effect any of the necessary governmental licenses required for the performance of its duties under this Agreement, including, but not limited to, its contract with CMS; and
- iv. **Breach of Material Term and Failure to Cure.** Plan's breach of any material term, covenant or condition of this Agreement, and subsequent failure to cure such breach as prescribed in Section 9.3 (c).
- **(b)** Cause for Termination of Agreement by Plan. The following shall constitute cause for termination of this Agreement by Plan:
  - i. **Failure to Maintain Insurance.** Provider fails to maintain adequate professional and general liability coverage required under this Agreement or to replace coverage that is cancelled or otherwise terminated;
  - ii. **Insolvency of Provider.** A petition is filed to declare Provider bankrupt or for reorganization under the bankruptcy laws of the United States or a receiver is appointed over all or any portion of Provider's assets;
  - iii. **Failure to Provide Quality Services.** Provider's failure to provide Contracted Services in accordance with the standards set forth in this Agreement, the standards of The Joint Commission or any other comparable accreditation organization and Plan's Quality Improvement and Utilization Management Programs;
  - iv. **Breach of Material Term and Failure to Cure.** Provider's breach of any material term, covenant or condition of this Agreement, and subsequent failure to cure such breach as prescribed in Section 9.3 (c).
- (c) Notice of Termination and Effective Date of Termination. The party asserting cause for termination of this Agreement (the "Terminating Party") shall provide written notice of termination to the other party. The notice of termination shall specify the breach or deficiency underlying the cause for termination. The party receiving the written notice of termination shall have thirty (30) calendar days from the receipt of such notice to cure the breach or deficiency to the satisfaction of the Terminating Party (the "Cure Period"). If such party fails to cure the breach or deficiency to the reasonable satisfaction of the Terminating Party within the Cure Period, or if the breach or deficiency is not curable, this Agreement shall terminate upon the expiration of the Cure Period. Satisfaction of a cure shall not be unreasonably withheld.
- **9.4 Termination of Provider.** Notwithstanding anything to the contrary in this Agreement, Plan shall have the right to sanction Provider or terminate this Agreement upon

ten (10) days' prior written notice in the event that Plan, or any federal or State agency reasonably believes that Provider is providing inadequate quality of care and/or Provider fails to comply with Plan's statutory obligations under the Knox-Keene Act or regulations whether the Plan directly manages and/or delegates responsibilities consistent with the Knox-Keene Act or Medicare and Medi-Cal laws and regulations. During said ten (10) day period, Provider shall cease providing Covered Services to Members.

# 9.5 Continuing Care Obligations of Provider.

- (a) General Obligations. In the event of termination of this Agreement for any cause or reason, Provider shall continue to provide Contracted Services to Members as required by law, including any Members who become eligible during the termination notice period, for a "Continuing Care Period", Plan shall pay Provider for Contracted Services provided by Provider during the Continuing Care Period at the rates set forth in Exhibit A-1, A-2, A-3, A-4, A-5 and A-6, Compensation Schedules, attached hereto.
- (b) Obligations if Plan Ceases Operating or Agreement is terminated for Nonpayment.
  - i. Notwithstanding any provisions of this Agreement to the contrary, Provider agrees that in the event Plan ceases operations for any reason, including insolvency, Provider shall continue to provide services as set forth in Section 9.5 (a) above and shall not bill, charge, collect or receive any form of payment from any Member for Covered Services provided by Provider after Plan ceases operations.
  - ii. In the event Plan ceases operations or Provider terminates this Agreement on the basis of Plan's failure to make timely payments in accordance with the terms of this Agreement, Provider shall continue to provide Services to those Enrollees who are under the care at the time Plan ceases operations or Provider terminates this Agreement until such Members are reassigned by Provider, as set forth in Section 9.5 (a) above and shall not bill, charge, collect or receive any form of payment from any Member for Covered Services.
- (c) Survival of Provisions Following Termination. Provider agrees that the provisions of this Section 9.5 (c) and the obligations of Provider shall survive termination of this Agreement regardless of the cause giving rise to such termination and shall be construed to be for the benefit of Members.

# **ARTICLE X**

# **DISPUTE RESOLUTION**

**10.1 Member Grievances and Appeals.** Provider shall review and process all complaints and grievances of Members through Grievance and Appeals Procedures established by Plan. Provider agrees to cooperate fully with Plan in the investigation and resolution of any such Member complaint.

**10.2 Dispute Resolution.** Controversies between Plan and Provider shall be resolved, to the extent possible, by informal meetings or discussions between appropriate representatives of the parties. Provider shall submit disputes to Plan in writing at the address set forth in the Provider Manual(s) and as set forth in this Agreement for resolution pursuant to Plan's dispute resolution procedures described in the Provider Manual(s) to the extent they are not in conflict with the terms and conditions contained herein this Agreement. In the event of any inconsistency between this Agreement and the Provider Manual(s), the terms and conditions of this Agreement shall prevail.

#### ARTICLE XI

# **GENERAL PROVISIONS**

- **11.1 Compliance with Applicable Law.** Provider and Plan shall comply with all Applicable Requirements, including any amendments or updates thereto. Any provision required to be in this Agreement according to the Applicable Requirements shall bind Plan and Provider whether or not specifically set forth in this Agreement.
- 11.2 Incorporation of Exhibits. Exhibits A-1, A-2, A-3, A-4, A-5, A-6, B (Reserved), C, D, E, F, G, and H are attached hereto and are hereby expressly incorporated herein by this reference.
- **11.3 Waiver.** The waiver by either party of a breach or violation of any provision of this Agreement shall not operate as or be construed to be a waiver of any subsequent breach thereof.
- **11.4 Assignment.** This Agreement shall not be assigned, delegated, or transferred by either Party without the prior written consent of the other Party, except that Plan may assign the Agreement to a parent or affiliate of the Plan that assumes the Plan's obligations as a licensed health care service plan. If required by law, any assignment or delegation of this Agreement shall be void unless prior written approval is obtained from the appropriate state or federal agencies.
- 11.5 Invalidity or Unenforceability. The invalidity or unenforceability of any terms or provisions hereof shall in no way affect the validity or enforceability of any other term or provision.
- **11.6 Amendment.** Except as set forth below, this Agreement may be modified only upon the mutual written consent of both Parties. Notwithstanding the foregoing, if Plan is required to amend this Agreement to comply with any state or federal law, regulation or instruction from any regulatory agency having jurisdiction over Plan's activities, Plan shall provide at least forty-five (45) days' prior written notice to Provider of such amendment. If Provider fails to accept such amendment within thirty (30) Plan has the option to terminate the Agreement immediately.
- **11.7 Governing Law.** This Agreement shall be governed in all respects by the laws of the State of California, and any applicable federal laws.

- 11.8 Interruption by Disasters. In the event the operations of Provider's facilities or any substantial portion thereof, are interrupted by war, fire, and other elements, insurrection, terrorism, riots, earthquakes, acts of God, or, without limiting the foregoing, any other cause beyond the control of Provider, the provisions of this Agreement (or such portions hereof as Provider is hereby rendered incapable of performing) may be suspended for the duration of such interruption. Such suspension shall be determined by the mutual written agreement of the Parties and shall include an identification of the necessary adjustments to any provision of this Agreement; provided, however, to the extent that services are provided by Provider, Plan shall compensate Provider for said services in accordance with Article IV herein. Should a substantial part of the services which Provider has agreed to provide hereunder be interrupted pursuant to such event(s) for a period in excess of thirty (30) days, Plan or Provider shall have the right to terminate this Agreement upon ten (10) days' prior written notice to the other party.
- **11.9 Headings.** The article and section headings used herein are for reference and convenience only and shall not enter into the interpretation hereof.
- 11.10 Solicitation of Plan Members, Subscribers or Subscriber Groups. Provider shall not engage in the practice of solicitation of Members, subscribers or subscriber groups without Plan's prior written consent. Solicitation shall mean conduct by an officer, agent, employee of Provider or their respective assignees or successors during the term of this Agreement or during the one (1) year immediately following the effective date of termination of this Agreement which may be reasonably interpreted as designed to persuade Members, subscribers or subscriber groups to disenroll from Plan or discontinue their relationship with Plan. Nothing in this Agreement shall be interpreted to discourage or prohibit Provider from discussing a Member's health care including, without limitation, communications regarding treatment options, alternative health plans or other coverage arrangements, unless such communications are for the primary purpose of securing financial gain.
- 11.11 Confidential and Proprietary Information. Both Parties agree to maintain confidential, (the "Confidential Information") as specified in the Section 11.11 and Section 11.12: (i) eligibility lists and any other information containing the names, addresses and telephone numbers of Members; (ii) the financial arrangements between either Party and any Provider; (iii) any other information compiled or created by either Party that is proprietary to either Party, and that either Party identifies as proprietary in writing. Neither Party shall disclose or use the Confidential Information for its own benefit or gain either during the term of this Agreement or after the date of termination of this Agreement. Either Party may use the Confidential Information to the extent necessary to perform its duties under this Agreement or upon express prior written permission of the other Party upon the effective date of termination of this Agreement, each Party shall promptly return to the other Party the Confidential Information in its possession, upon the other Party's notice. Both Parties shall maintain the confidentiality of the rates and special terms of this Agreement that are unique to the other Party. The obligations contained in this Section 11.11 shall survive the termination of this Agreement.
- **11.12 California Public Records Act.** The County is a public agency subject to the disclosure requirements of the California Public Records Act ("CPRA"). If Provider's proprietary information is contained in documents submitted to Plan, and Provider claims

that such information falls within one or more CPRA exemptions, Provider must clearly mark such information "CONFIDENTIAL AND PROPRIETARY," and identify the specific lines containing the information. In the event of a request for such information, the Plan will make best efforts to provide notice to Provider prior to such disclosure. If Provider contends that any documents are exempt from the CPRA and wishes to prevent disclosure, it is required to obtain a protective order, injunctive relief or other appropriate remedy from a court of law in Santa Clara County before the Plan's deadline for responding to the CPRA request. If Provider fails to obtain such remedy within Plan's deadline for responding to the CPRA request, Plan may disclose the requested information.

11.13 Notices. All notices, requests, demands and other communications hereunder shall be in writing (hereafter a "Notice"). A Notice shall be deemed given when delivered (i) delivered in person, or (ii) four (4) days after being mailed by certified or registered mail, postage prepaid, return receipt requested, or (iii) one (1) day after being sent by overnight courier such as Federal Express, to the Parties, their successors in interest or their assignees at the following addresses, or at such other addresses as the Parties may designate by written Notice in the manner aforesaid. In addition to the approved delivery methods, a copy of the Notice shall also be sent via secure email or electronic facsimile as follows:

Provider:	Plan:
Provider Contact Name, Title	Bruce Butler, Chief Executive Officer
Provider Contract Name	Valley Health Plan
«Address»	2480 North First Street, Suite 160
«City», «State» «Zip»	San Jose, CA 95131
Phone #	(408) 885-5780
Email	,
	And CC:
	Valley Health Plan
	Provider Contracts Administration
	2480 North First Street, Suite 160
	San Jose, CA 95131
	ProviderContracts@vhp.sccgov.org

11.14 Free Exchange of Information. No provision of this Agreement shall be construed to prohibit, nor shall any provision in any contract between Provider and its employees or subcontractors prohibit, the free, open and unrestricted exchange of any and all information of any kind between a Provider and Members regarding the nature of the Member's medical condition, the health care treatment options and alternatives available and their relative risks and benefits, whether or not covered or excluded under the Member's health plan, and the Member's right to appeal any adverse decision made by Provider or Plan regarding coverage of treatment that has been recommended or rendered. Moreover, Provider and Plan agree not to penalize nor sanction any Provider in any way for engaging in such free, open and unrestricted communication with a Member nor for advocating for a particular service on a Member's behalf.

Fax: (408) 954-1027

- **11.15 Severability.** If any provision of this Agreement is held by a court of competent jurisdiction or applicable state or federal law and their implementing regulations to be invalid, void or unenforceable, the remaining provisions shall nevertheless continue in full force and effect.
- **11.16 Attorneys' Fees.** Should either party institute any action or procedure to enforce this Agreement or any provision hereof, or for damages by reason of any alleged breach of this Agreement or of any provision hereof, or for a declaration of rights hereunder (including, without limitation, arbitration), each party shall pay its own costs and expenses, including, without limitation, its own attorneys' fees, incurred in connection with such action or proceeding.
- **11.17 No Third-Party Beneficiaries.** This Agreement shall not create any rights in any third-parties who have not entered into this Agreement, nor shall this Agreement entitle any such third-party to enforce any rights or obligations that may be possessed by such third-party.
- **11.18 Integration of Entire Agreement.** This Agreement contains all the terms and conditions agreed upon by the Parties regarding the subject matter of this Agreement. Any prior agreements, promises, negotiations or representations of or between the Parties, either oral or written, relating to the subject matter of this Agreement, which are not expressly set forth in this Agreement are null and void and of no further force or effect.
- 11.19 County No Smoking Policy. Provider and its employees, agents and subcontractors, shall comply with the County's No Smoking Policy, as set forth in the Board of Supervisors Policy Manual section 3.47 (as amended from time to time), which prohibits smoking: (i) at the Santa Clara Valley Medical Center campus and all County-owned and operated health facilities, (ii) within 30 feet surrounding County-owned buildings and leased buildings where the County is the sole occupant, and (iii) in all County vehicles.
- **11.20 Food and Beverage Standards.** Except in the event of an emergency or medical necessity, the following nutritional standards shall apply to any foods and/or beverages purchased by Provider with County funds for County-sponsored meetings or events:
  - (a) If food is to be provided, healthier food options shall be offered. "Healthier food options" include (i) fruits, vegetables, whole grains, and low fat and low-calorie foods; (ii) minimally processed foods without added sugar and with low sodium; (iii) foods prepared using healthy cooking techniques; and (iv) foods with less than 0.5 grams of trans fat per serving. Whenever possible, Provider shall (i) offer seasonal and local produce; (ii) serve fruit instead of sugary, high calorie desserts; (iii) attempt to accommodate special, dietary and cultural needs; and (iv) post nutritional information and/or a list of ingredients for items served. If meals are to be provided, a vegetarian option shall be provided, and the Contractor should consider providing a vegan option. If pre-packaged snack foods are provided, the items shall contain: (i) no more than 35% of calories from fat, unless the snack food items consist solely of nuts or seeds; (ii) no more than 10% of calories from saturated fat; (iii) zero trans-fat; (iv) no more than 35% of total weight from sugar and

caloric sweeteners, except for fruits and vegetables with no added sweeteners or fats; and (v) no more than 360 mg of sodium per serving.

- (b) If beverages are to be provided, beverages that meet the County's nutritional criteria are (i) water with no caloric sweeteners; (ii) unsweetened coffee or tea, provided that sugar and sugar substitutes may be provided as condiments; (iii) unsweetened, unflavored, reduced fat (either nonfat or 1% low fat) dairy milk; (iv) plant-derived milk (e.g., soy milk, rice milk, and almond milk) with no more than 130 calories per 8 ounce serving; (v) 100% fruit or vegetable juice (limited to a maximum of 8 ounces per container); and (vi) other low-calorie beverages (including tea and/or diet soda) that do not exceed 40 calories per 8 ounce serving. Sugar-sweetened beverages shall not be provided.
- **11.21** Assignment of Clayton Act, Cartwright Act Claims. Provider hereby assigns to the Plan all rights, title, and interest in and to all causes of action it may have under Section 4 of the Clayton Act (15 U.S.C. Sec. 15) or under the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), arising from purchases of goods, materials, or services by the Provider for sale to the Plan pursuant to this Agreement.

## 11.22 Compliance with All Laws, Including Nondiscrimination, Equal Opportunity, and Wage Theft Prevention.

- (a) <u>Compliance with All Laws.</u> Provider shall comply with all applicable Federal, State, and local laws, regulations, rules, and policies (collectively, "Laws"), including but not limited to the non-discrimination, equal opportunity, and wage and hour Laws referenced in the paragraphs below.
- Compliance with Non-Discrimination and Equal Opportunity Laws: (b) Provider shall comply with all applicable Laws concerning nondiscrimination and equal opportunity in employment and contracting, including but not limited to the following: Santa Clara County's policies for Providers on nondiscrimination and equal opportunity; Title VII of the Civil Rights Act of 1964 as amended; Americans with Disabilities Act of 1990; the Age Discrimination in Employment Act of 1967; the Rehabilitation Act of 1973 (Sections 503 and 504); the Equal Pay Act of 1963; California Fair Employment and Housing Act (Gov. Code § 12900 et seq.); California Labor Code sections 1101, 1102, and 1197.5; and the Genetic Information Nondiscrimination Act of 2008. In addition to the foregoing, Provider shall not discriminate against any subcontractor, employee, or applicant for employment because of age, race, color, national origin, ancestry, religion, sex, gender identity, gender expression, sexual orientation, mental disability, physical disability, medical condition, political belief, organizational affiliation, or marital status in the recruitment, selection for training (including but not limited to apprenticeship), hiring, employment, assignment, promotion, layoff, rates of pay or other forms of compensation. Nor shall Provider discriminate in the provision of services provided under this contract because of age, race, color, national origin, ancestry, religion, sex, gender identity, gender expression, sexual orientation, mental disability, physical disability, medical condition, political beliefs, organizational affiliations, or marital status.

- (c) <u>Compliance with Wage and Hour Laws</u>: Provider shall comply with all applicable wage and hour Laws, which may include but are not limited to, the Federal Fair Labor Standards Act, the California Labor Code, and, if applicable, any local minimum wage, prevailing wage, or living wage Laws.
- (d) Definitions: For purposes of this Subsection 11.22, the following definitions shall apply. A "Final Judgment" shall mean a judgment, decision, determination, or order (i) which is issued by a court of law, an investigatory government agency authorized by law to enforce an applicable Law, an arbiter, or arbitration panel and (ii) for which all appeals have been exhausted or the time period to appeal has expired. For pay equity Laws, relevant investigatory government agencies include the federal Equal Employment Opportunity Commission, the California Division of Labor Standards Enforcement, and the California Department of Fair Employment and Housing. Violation of a pay equity Law shall mean unlawful discrimination in compensation on the basis of an individual's sex, gender, gender identity, gender expression, sexual orientation, race, color, ethnicity, or national origin under Title VII of the Civil Rights Act of 1964 as amended, the Equal Pay Act of 1963, California Fair Employment and Housing Act, or California Labor Code section 1197.5, as applicable. For wage and hour Laws, relevant investigatory government agencies include the federal Department of Labor, the California Division of Labor Standards Enforcement, and the City of San Jose's Office of Equality Assurance.
- **(e)** Prior Judgments, Decisions or Orders against Provider: By signing this Agreement, Provider affirms that it has disclosed any final judgments that (i) were issued in the five (5) years prior to executing this Agreement by a court, an investigatory government agency, arbiter, or arbitration panel and (ii) found that Provider violated an applicable wage and hour law or pay equity law. Provider further affirms that it has satisfied and complied with or has reached Agreement with the County regarding the manner in which it will satisfy any such final judgments.
- Violations of Wage and Hour Laws or Pay Equity Laws during Term of (f) Contract: If at any time during the term of this Agreement, Provider receives a Final Judgment rendered against it for violation of an applicable wage and hour Law or pay equity Law, then Provider shall promptly satisfy and comply with any such Final Judgment. Provider shall inform the Office of the County Executive-Office of Countywide Contracting Management (OCCM) of any relevant Final Judgment against it within 30 days of the Final Judgment becoming final or of learning of the Final Judgment, whichever is later. Provider shall also provide any documentary evidence of compliance with the Final Judgment within 5 days of satisfying the Final Judgment. Any notice required by this paragraph shall be addressed to the Office of the County Executive-OCCM at 70 W. Hedding Street, East Wing, 11th Floor, San José, CA 95110. Notice provisions in this paragraph are separate from any other notice provisions in this Agreement and, accordingly, only notice provided to the Office of the County Executive-OCCM satisfies the notice requirements in this paragraph.

- (g) Access to Records Concerning Compliance with Pay Equity Laws: In addition to and notwithstanding any other provision of this Agreement concerning access to Provider's records, Provider shall permit the County and/or its authorized representatives to audit and review records related to compliance with applicable pay equity Laws. Upon the County's request, Provider shall provide the County with access to any and all facilities and records, including but not limited to financial and employee records that are related to the purpose of this Subsection 11.22, except where prohibited by federal or state laws, regulations or rules. County's access to such records and facilities shall be permitted at any time during Provider's normal business hours upon no less than 10 business days' advance notice.
- (h) Pay Equity Notification: Provider shall (i) at least once in the first year of this Agreement and annually thereafter, provide each of its employees working in California and each person applying to Provider for a job in California (collectively, "Employees and Job Applicants") with an electronic or paper copy of all applicable pay equity Laws or (ii) throughout the term of this Agreement, continuously post an electronic copy of all applicable pay equity Laws in conspicuous places accessible to all of Provider's Employees and Job Applicants.
- (i) <u>Material Breach</u>: Failure to comply with any part of this Subsection 11.22 shall constitute a material breach of this Agreement. In the event of such a breach, the County may, in its discretion, exercise any or all remedies available under this Agreement and at law. County may, among other things, take any or all of the following actions:
  - i. Suspend or terminate any or all parts of this Agreement.
  - ii. Withhold payment to Provider until full satisfaction of a Final Judgment concerning violation of an applicable wage and hour Law or pay equity Law.
    - iii. Offer Provider an opportunity to cure the breach.
- (j) <u>Subcontractors</u>: Provider shall impose all of the requirements set forth in this Subsection 11.22 on any subcontractors permitted to perform work under this Agreement. This includes ensuring that any subcontractor receiving a Final Judgment for violation of an applicable Law promptly satisfies and complies with such Final Judgment.
- 11.23 Contracting Principles. All entities that contract with the County to provide services where the contract value is \$100,000 or more per budget unit per fiscal year and/or as otherwise directed by the Board of Supervisors, shall be fiscally responsible entities and shall treat their employees fairly. To ensure compliance with these contracting principles, all Providers shall: (i) comply with all applicable federal, state and local rules, regulations and laws; (ii) maintain timekeeping and expense records, and make those records available upon request; (iii) provide to the County unaudited balance sheet and financial information; (iv) upon County's request, provide County reasonable access, through representatives of Provider, to facilities, timekeeping and expense records that are related to the purpose of the Agreement, except where prohibited by federal or state laws, regulations or rules.

**11.24 Electronic Signature**. Unless otherwise prohibited by law or County policy, the parties agree that an electronic copy of a signed contract, or an electronically signed contract, has the same force and legal effect as a contract executed with an original ink signature. The term "electronic copy of a signed contract" refers to a transmission by facsimile, electronic mail, or other electronic means of a copy of an original signed contract in a portable document format. The term "electronically signed contract" means a contract that is executed by applying an electronic signature using technology approved by the County.

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives effective as the Effective Date.

Provider_Contract_Name		County of Santa Clara dba Valley Health Plan		
Signing_Authority's_Name Title	Date	Bruce Butler Chief Executive Officer, Valley Ho	Date ealth Plan	
«Taxld»		Approved By:		
TAX ID #		Jeffrey V. Smith, MD, JD	Date	
Billing NPI #		County Executive		
NDI #		Approved as to form and legality:		
NPI#				
		Jennifer S. Sprinkles Deputy County Counsel	Date	

#### **Exhibits incorporated into Agreements:**

Exhibit A-1	Compensation Schedule – Employer Group-Classic
Exhibit A-2	Compensation Schedule – Employer Group-Preferred
Exhibit A-3	Compensation Schedule – Covered California and Individual & Family Plan
Exhibit A-4	Compensation Schedule – Medi-Cal Managed Care
Exhibit A-5	Compensation Schedule – Healthy Kids
Exhibit A-6	Compensation Schedule – County Responsibility Patients
Exhibit B	RESERVED
Exhibit C	List of Individual Providers & Sites
Exhibit D	Contacts for Prior Authorization
Exhibit E	Insurance & Indemnity Requirements
Exhibit F	Language Assistance Program Requirements
Exhibit G	Timely Access Standards
Exhibit H	Covered CA Requirements

## EXHIBIT A-1 COMPENSATION SCHEDULE Line of Business: Commercial Product: Employer Group-Classic

#### PROVIDER\_CONTRACT\_NAME

#### **BILLING:**

Provider shall submit Clean Claims in an electronic format approved by Plan within ninety (90) days of the date in which service was rendered. A Clean Claim must include, without limitation, the patient's name, patient identification number, the service(s) provided, the date(s) services were rendered, and the charge(s) as required by this Agreement or in the Provider Manual available on the VHP website: www.valleyhealthplan.org.

Claims shall be submitted electronically to Plan via Utah Health Information Network (UHIN), Plan's EDI clearinghouse as set forth below:

VHP's Trading Partner Number: HT007700-001 Customer Service Number: 877-693-3071

In the event Plan permits an exception to electronic claims submission, approved written format claims shall be submitted appropriately to the address below:

VHP Commercial P.O. Box 26160 San Jose, CA 95159

#### **PAYMENT:**

All of the rates are as defined and are subject to payment rules including **Coordination of Benefits** and base calculations as delineated in the Plan Member's Evidence of Coverage (EOC).

Covered Services that are within Provider's scope of practice and provided to a Member pursuant to the EOC in effect at the time services are rendered shall be compensated in accordance with this Agreement.

Plan agrees to pay Provider for Medically Necessary Covered Services provided to Members at the rates set forth below, less any applicable Co-payments collected from Member, pursuant to this Agreement:

Covered Services provided in accordance with Plan's Authorization procedures shall be reimbursed in accordance with the Centers for Medicare and Medicaid Services (CMS), Medicare billing and reimbursement guidelines, including any applicable reductions and/or discounts, which may be amended by CMS from time to time. Covered Services shall be reimbursed by Plan at the lessor of Provider's billed charges or at one hundred percent (100%) of the applicable and prevailing Medicare rate, less applicable reductions for the Region where services were provided, as of the date services were rendered.

Covered Services for which there are no CMS defined billing and reimbursement guidelines or for which Medicare has not established a rate and which are eligible for payment using industry standard coding and billing conventions shall be reimbursed at twenty-five percent (25%) of Provider's usual and customary billed charges.

## EXHIBIT A-2 COMPENSATION SCHEDULE Line of Business: Commercial Product: Employer Group-Preferred

#### PROVIDER\_CONTRACT\_NAME

#### **BILLING:**

Provider shall submit Clean Claims in an electronic format approved by Plan within ninety (90) days of the date in which service was rendered. A Clean Claim must include, without limitation, the patient's name, patient identification number, the service(s) provided, the date(s) services were rendered, and the charge(s) as required by this Agreement or in the Provider Manual available on the VHP website: <a href="https://www.valleyhealthplan.org">www.valleyhealthplan.org</a>.

Claims shall be submitted electronically to Plan via Utah Health Information Network (UHIN), Plan's EDI clearinghouse as set forth below:

VHP's Trading Partner Number: HT007700-001 Customer Service Number: 877-693-3071

In the event Plan permits an exception to electronic claims submission, approved written format claims shall be submitted appropriately to the address below:

VHP Commercial P.O. Box 26160 San Jose, CA 95159

#### **PAYMENT:**

All of the rates are as defined and are subject to payment rules including **Coordination of Benefits** and base calculations as delineated in the Plan Member's Evidence of Coverage (EOC).

Covered Services that are within Provider's scope of practice and provided to a Member pursuant to the EOC in effect at the time services are rendered shall be compensated in accordance with this Agreement.

Plan agrees to pay Provider for Medically Necessary Covered Services provided to Members at the rates set forth below, less any applicable Co-payments collected from Member, pursuant to this Agreement:

Covered Services provided in accordance with Plan's Authorization procedures shall be reimbursed in accordance with the Centers for Medicare and Medicaid Services (CMS), Medicare billing and reimbursement guidelines, including any applicable reductions and/or discounts, which may be amended by CMS from time to time. Covered Services shall be reimbursed by Plan at the lessor of Provider's billed charges or at one hundred percent (100%) of the applicable and prevailing Medicare rate, less applicable reductions for the Region where services were provided, as of the date services were rendered.

Covered Services for which there are no CMS defined billing and reimbursement guidelines or for which Medicare has not established a rate and which are eligible for payment using industry standard coding and billing conventions shall be reimbursed at twenty-five percent (25%) of Provider's usual and customary billed charges.

## EXHIBIT A-3 COMPENSATION SCHEDULE Line of Business: Commercial

**Product: Covered California and Individual & Family Plan** 

#### PROVIDER\_CONTRACT\_NAME

#### **BILLING:**

Provider shall submit Clean Claims in an electronic format approved by Plan within ninety (90) days of the date in which service was rendered. A Clean Claim must include, without limitation, the patient's name, patient identification number, the service(s) provided, the date(s) services were rendered, and the charge(s) as required by this Agreement or in the Provider Manual available on the VHP website: <a href="https://www.valleyhealthplan.org">www.valleyhealthplan.org</a>.

Claims shall be submitted electronically to Plan via Utah Health Information Network (UHIN), Plan's EDI clearinghouse as set forth below:

VHP's Trading Partner Number: HT007700-001 Customer Service Number: 877-693-3071

In the event Plan permits an exception to electronic claims submission, approved written format claims shall be submitted appropriately to the address below:

VHP Covered California / IFP P.O. Box 26160 San Jose, CA 95159

#### **PAYMENT:**

All of the rates are as defined and are subject to payment rules including **Coordination of Benefits** and base calculations as delineated in the Plan Member's Evidence of Coverage (EOC).

Covered Services that are within Provider's scope of practice and provided to a Member pursuant to the EOC in effect at the time services are rendered shall be compensated in accordance with this Agreement.

Plan agrees to pay Provider for Medically Necessary Covered Services provided to Members at the rates set forth below, less any applicable Co-payments collected from Member, pursuant to this Agreement:

Covered Services provided in accordance with Plan's Authorization procedures shall be reimbursed in accordance with the Centers for Medicare and Medicaid Services (CMS), Medicare billing and reimbursement guidelines, including any applicable reductions and/or discounts, which may be amended by CMS from time to time. Covered Services shall be reimbursed by Plan at the lessor of Provider's billed charges or at one hundred percent (100%) of the applicable and prevailing Medicare rate, less applicable reductions for the Region where services were provided, as of the date services were rendered.

Covered Services for which there are no CMS defined billing and reimbursement guidelines or for which Medicare has not established a rate and which are eligible for payment using industry standard coding and billing conventions shall be reimbursed at twenty-five percent (25%) of Provider's usual and customary billed charges.

# EXHIBIT A-4 COMPENSATION SCHEDULE Line of Business: Government Product: Medi-Cal Managed Care

#### PROVIDER\_CONTRACT\_NAME

#### **BILLING**

- (a) Provider shall submit Clean Claims for all Contracted Services rendered to a Member, within six (6) months in which services were rendered, pursuant to this Agreement within the requirements set forth below:
- **(b)** VHP Medi-Cal Managed Care: Original (or initial) Medi-Cal claims must be received within six months following the month in which services were rendered. This requirement is referred to as the sixmonth billing limit. Exceptions to the six-month billing limit can be made if the reason for the late billing is one of the delay reasons allowed by regulations. Claims that are not received within the six-month billing limit and do not meet any of the other delay reasons are subject to be reimbursed at a reduced rate or will be denied as follows, in compliance with *California Welfare and Institutions Code*, *Section 14115*.
  - Claims received during the <u>seventh through ninth month</u> after the month of service will be reimbursed at 75 percent of the payable amount.
  - Claims received during the <u>tenth through twelfth month</u> after the month of service will be reimbursed at 50 percent of the payable amount.
  - Claims received after the twelfth month following the month of service will be denied.
- **(c)** Claims Submission. Provider shall submit Clean Claims in an electronic format approved by Plan. A Clean Claim must include, without limitation, the patient's name, patient identification number, the service(s) provided, the date(s) services were rendered, and the charge(s).
  - Electronic Clean Claims shall be submitted to Plan via Utah Health Information Network (UHIN), Plan's EDI clearinghouse as set forth below:

VHP's Trading Partner Number: HT007700-001 Customer Service Number: 877-693-3071

Further information can be located within the VHP Provider Manual or by contacting the Plan's Provider Relations Department at 408-885-2221.

In the event Plan permits an exception to electronic claims submission, approved written format claims shall be submitted appropriately as follows:

VHP Medi-Cal Managed Care P.O. Box 28407 San Jose. CA 95159

#### **PAYMENT**

All of the rates are as defined and are subject to payment rules including **Coordination of Benefits** and base calculations as delineated in the Member's Evidence of Coverage (EOC).

Covered Services that are within Provider's scope of practice and provided to a Member pursuant to the EOC in effect at the time services are rendered shall be compensated in accordance with this Agreement.

Plan agrees to pay Provider for Medically Necessary Covered Services provided to Members at the following rates, less any applicable Co-payments collected from Member, pursuant to this Agreement:

Covered Services provided in accordance with Plan's Authorization procedures shall be reimbursed in accordance with the California Department of Health Care Services (DHCS) Medi-Cal billing and

reimbursement guidelines, including any applicable reductions, which may be amended by DHCS from time to time. Covered Services shall be reimbursed by Plan at the lessor of Provider's billed charges or at one hundred percent (100%) of the applicable Medi-Cal Fee Schedule, less applicable reductions in effect on the date services are rendered.

Covered Services for which there are no DHCS defined billing and reimbursement guidelines or for which Medi-Cal has not established a rate and which are eligible for payment utilizing industry standard coding and billing conventions, shall be reimbursed at twenty-five percent (25%) of Provider's usual and customary billed charges.

# EXHIBIT A-5 COMPENSATION SCHEDULE Line of Business: Government Product: Healthy Kids

#### PROVIDER\_CONTRACT\_NAME

#### **BILLING**

- (a) Provider shall submit Clean Claims for all Contracted Services rendered to a Member, within six (6) months in which services were rendered, pursuant to this Agreement within the requirements set forth below:
- **(b)** VHP Healthy Kids: Original (or initial) Healthy Kids claims must be received within six months following the month in which services were rendered. This requirement is referred to as the six-month billing limit. Exceptions to the six-month billing limit can be made if the reason for the late billing is one of the delay reasons allowed by regulations. Claims that are not received within the six-month billing limit and do not meet any of the other delay reasons are subject to be reimbursed at a reduced rate or will be denied as follows, in compliance with *California Welfare and Institutions Code*, *Section 14115*.
  - Claims received during the <u>seventh through ninth month</u> after the month of service will be reimbursed at 75 percent of the payable amount.
  - Claims received during the <u>tenth through twelfth month</u> after the month of service will be reimbursed at 50 percent of the payable amount.
  - Claims received after the twelfth month following the month of service will be denied.
- **(c)** Claims Submission. Provider shall submit Clean Claims in an electronic format approved by Plan. A Clean Claim must include, without limitation, the patient's name, patient identification number, the service(s) provided, the date(s) services were rendered, and the charge(s).
  - Electronic Clean Claims shall be submitted to Plan via Utah Health Information Network (UHIN), Plan's EDI clearinghouse as set forth below:

VHP's Trading Partner Number: HT007700-001 Customer Service Number: 877-693-3071

Further information can be located within the VHP Provider Manual or by contacting the Plan's Provider Relations Department at 408-885-2221.

In the event Plan permits an exception to electronic claims submission, approved written format claims shall be submitted appropriately as follows:

VHP Healthy Kids P.O. Box 28410 San Jose, CA 95159

#### **PAYMENT**

All of the rates are as defined and are subject to payment rules including **Coordination of Benefits** and base calculations as delineated in the Member's Evidence of Coverage (EOC).

Covered Services that are within Provider's scope of practice and provided to a Member pursuant to the EOC in effect at the time services are rendered shall be compensated in accordance with this Agreement.

Plan agrees to pay Provider for Medically Necessary Covered Services provided to Members at the following rates, less any applicable Co-payments collected from Member, pursuant to this Agreement:

Covered Services provided in accordance with Plan's Authorization procedures shall be reimbursed in accordance with the California Department of Health Care Services (DHCS) Medi-Cal billing and

reimbursement guidelines, including any applicable reductions, which may be amended by DHCS from time to time. Covered Services shall be reimbursed by Plan at the lessor of Provider's billed charges or at one hundred percent (100%) of the applicable Medi-Cal Fee Schedule, less applicable reductions in effect on the date services are rendered.

Covered Services for which there are no DHCS defined billing and reimbursement guidelines or for which Medi-Cal has not established a rate and which are eligible for payment utilizing industry standard coding and billing conventions, shall be reimbursed at twenty-five percent (25%) of Provider's usual and customary billed charges.

## EXHIBIT A-6 COMPENSATION SCHEDULE Line of Business: Coverage Program

Product: County Responsibility Patients

#### PROVIDER\_CONTRACT\_NAME

#### **BILLING:**

Provider shall submit Clean Claims in an electronic or written format approved by Plan within ninety (90) days of the date in which service was rendered. A Clean Claim must include, without limitation, the patient's name, patient identification number, the service(s) provided, the date(s) services were rendered, and the charge(s) as required by this Agreement or in the Provider Manual available on the VHP website: www.valleyhealthplan.org.

Approved written format claims shall be submitted appropriately to the address below:

Valley Health Plan VMC / APD Claims 2480 N. First St., Suite 160 San Jose, CA 95131

#### **PAYMENT:**

All of the rates are as defined and are subject to payment rules including **Coordination of Benefits** and base calculations as delineated in the Member's Evidence of Coverage (EOC).

Covered Services that are within Provider's scope of practice and provided to a Member pursuant to the EOC in effect at the time services are rendered shall be compensated in accordance with this Agreement.

County agrees to pay Provider for Medically Necessary Covered Services provided to Members at the rates set forth below, less any applicable Co-payments collected from Member, pursuant to this Agreement:

Authorized Covered Services shall be reimbursed at one hundred percent (100%) of the applicable and prevailing Medi-Cal Fee Schedule as of the date services were rendered.

Authorized Covered Services billed with a valid code for which Medi-Cal does not report a prevailing rate, will be reimbursed at twenty-five percent (25%) of billed charges.

### EXHIBIT C LIST OF INDIVIDUAL PROVIDERS & SITES

#### PROVIDER\_CONTRACT\_NAME

The following list includes the most current roster submitted by Provider as of the Agreement's Effective Date. Updates thereto shall be provided in accordance with Section 2.9 of this Agreement.

Name	Address	Phone No.	NPI # / Type	License Type	License No. & Expiration date

# EXHIBIT D CONTACTS FOR PRIOR AUTHORIZATION OF COVERED SERVICE PROVIDER\_CONTRACT\_NAME

#### **Valley Health Plan Customer Service Department**

- **1-888-421-8444**, select **option 4** for *VHP Customer Service Department* Select **option 2** to check *Benefits\*, Coverage\*, Eligibility, & Authorization Status'*.
  - Specify to representative the MEMBER's Plan ID#

\*Questions for Medi-Cal and Healthy Kids Members, relating to benefits, coverage limitation/exclusions, and/or description of covered services will be redirected to SCFHP.

Emergency Department to notify Plan immediately post stabilization by calling 855-254-8264

For further information regarding VHP's Authorization and Referrals Process, please reference the Provider Manual which can be located on the VHP Website at <a href="https://www.valleyhealthplan.org/sites/p/manual/Pages/home.aspx">https://www.valleyhealthplan.org/sites/p/manual/Pages/home.aspx</a>.

## EXHIBIT E INSURANCE & INDEMNITY REQUIREMENTS FOR VHP MEDICAL PROVIDER

#### PROVIDER\_CONTRACT\_NAME

#### **Indemnity**

The Provider shall indemnify, defend, and hold harmless the County of Santa Clara (hereinafter "County"), its officers, agents and employees from any claim, liability, loss, injury or damage arising out of or in connection with, performance of this Agreement by Provider and/or its agents, employees or sub-Providers, excepting only loss, injury or damage caused by the sole negligence or willful misconduct of personnel employed by the County. It is the intent of the Parties to this Agreement to provide the broadest possible coverage For the County. The Provider shall reimburse the County for all costs, attorneys' fees, expenses and liabilities incurred with respect to any litigation in which the Provider is obligated to indemnify, defend and hold harmless the County under this Agreement.

#### <u>Insurance</u>

Without limiting the Provider's indemnification of the County, the Provider shall provide and maintain at its own expense, during the term of this Agreement, or as may be further required herein, the following insurance coverages and provisions:

#### A. Evidence of Coverage

Prior to commencement of this Agreement, the Provider shall provide a Certificate of Insurance certifying that coverage as required herein has been obtained. Individual endorsements executed by the insurance carrier shall accompany the certificate. In addition, a certified copy of the policy or policies shall be provided by the Provider upon request. The Certificate of Insurance shall list the certificate holder as follows:

County of Santa Clara c/o EBIX RCS, Inc. P.O. Box 257 Portland, MI USA 48875

This verification of coverage shall be sent to the requesting County department, unless otherwise directed. The Provider shall not receive a Notice to Proceed with the work under the Agreement until it has obtained all insurance required and such insurance has been approved by the County. This approval of insurance shall neither relieve nor decrease the liability of the Provider.

#### B. Qualifying Insurers

All coverages, except surety, shall be issued by companies which hold a current policy holder's alphabetic and financial size category rating of not less than A-V, according to the current Best's Key Rating Guide or a company of equal financial stability that is approved by the County's Insurance Manager.

#### C. Notice of Cancellation

All coverage as required herein shall not be canceled or changed so as to no longer meet the specified County insurance requirements without 30 days' prior written notice of such cancellation or change being delivered to the County of Santa Clara or their designated agent.

#### D. Insurance Required

 Commercial General Liability Insurance - for bodily injury (including death) and property damage which provides limits as follows:

a. Each occurrence - \$1,000,000
 b. General aggregate - \$2,000,000
 c. Personal Injury - \$1,000,000

#### 2. General liability coverage shall include:

- a. Premises and Operations
- b. Personal Injury liability
- c. Severability of interest

#### 3. Workers' Compensation and Employer's Liability Insurance

- Statutory California Workers' Compensation coverage including broad form allstates coverage.
- b. Employer's Liability coverage for not less than one million dollars (\$1,000,000) per occurrence.

#### 4. Professional Errors and Omissions Liability Insurance

- a. Coverage shall be in an amount of not less than one million dollars (\$1,000,000) per occurrence/aggregate.
- b. If coverage contains a deductible or sell-retention, it shall not be greater than fifty thousand dollars (\$50,000) per occurrence/event.
- c. Coverage as required herein shall be maintained for a minimum of two years following termination or completion of this Agreement.

#### 5. Claims Made Coverage

If coverage is written on a claim made basis, the Certificate of Insurance shall dearly state so. In addition to coverage requirements above, such policy shall provide that:

- a. Policy retroactive date coincides with or precedes the Provider's start of work (including subsequent policies purchased as renewals or replacements).
- b. Policy allows fix reporting of circumstances or incidents that might give rise to future claims.

#### E. Special Provisions

The following provisions shall apply to this Agreement:

- 1. The foregoing requirements as to the types and limits of insurance coverage to be maintained by the Provider and any approval of said insurance by the County or its insurance consultant(s) are not intended to and shall not in any manner limit or qualify the liabilities and obligations otherwise assumed by the Provider pursuant to this Agreement, including but not limited to, the provisions concerning indemnification.
- 2. The County acknowledges that some insurance requirements contained in this Agreement may be fulfilled by self-insurance on the part of the Provider. However, this shall not in any way limit liabilities assumed by the Provider under this Agreement. Any self-insurance shall be approved in writing by the County upon satisfactory evidence of financial capacity. Provider's obligation hereunder may be satisfied in whole or in part by adequately funded self-insurance programs or self-insurance retentions.
- **3.** Should any of the work under this Agreement be sublet, the Provider shall require each of its subcontractors of any tier to carry the aforementioned coverages, or Provider may insure subcontractors under its own policies.
- **4.** The County reserves the right to withhold payments to the Provider in the event of material noncompliance with the insurance requirements outlined above.

#### **Acknowledgement of Insurance Requirements**

I, <u>Signing Authority's Name</u> , on behalf of <u>Provide</u> understand the terms and conditions of the Insurance Agreement. I understand that all Insurance certificate services rendered. I understand that if <u>Provider Continued</u> these insurance requirements, <u>Provider Contract</u> services rendered until insurance certification is obtated forth in this agreement. In addition, if <u>Provider Continued</u> insurance certification in a timely manner, this agreement.	e Requirements under this es MUST be in effect, prior to the ntract Name is not compliant with Name will not be compensated for ined that meets the requirements set tract Name fails to obtain the required
Signature	 Date

### EXHIBIT F LANGUAGE ASSISTANCE PROGRAM REQUIREMENTS

#### PROVIDER CONTRACT NAME

Without limiting any of other obligations of the Parties under this Agreement, the Parties shall comply with such regulatory requirements of the Health Care Language Assistance Act, pursuant to Health and Safety Code Section 1367.04 et seq. and California Code of Regulations ("CCR") 28 CCR 1300.67.04 et seq., key provisions of which are summarized in this exhibit. To the extent that the provisions in this exhibit are inconsistent with provisions in the Agreement, the terms in this exhibit shall prevail as to the obligations of the Parties under the Health Care Language Assistance Act ("Act").

#### Plan Responsibilities:

- Plan shall provide a copy of the Plan's Language Assistance Program requirements and all written policies and procedures regarding the Language Assistance Program and the Act.
- Plan shall ensure that the threshold language needs of Plan Members are identified and made available to Provider. Provide list of covered languages and update list as necessary.
- Plan shall generate and periodically update a list of vital documents that Provider shall translate in threshold languages. Vital documents are those documents that contain information that is critical for accessing medical services and/or benefits and are identified in the Plan's operating guidelines and provided to Provider.
- Plan will monitor and audit Provider regarding compliance with language assistance requirements.

#### **Provider Responsibilities:**

- Provider agrees to provide or arrange for the provision of qualified interpretation services to Limited English Proficiency (LEP) Members, in threshold languages, at no cost to the Member. Provider shall comply with Plan's Language Assistance Program requirements, policies and procedures so long as they conform to Provider's own Language Assistance Policies and applicable law.
- Provider agrees to provide or arrange for the translation of vital documents in threshold languages.
- Provider will document in the medical record if patient authorizes use of family member as an interpreter.

### EXHIBIT G TIMELY ACCESS STANDARDS

#### PROVIDER\_CONTRACT\_NAME

#### I. Appointments

a. To ensure members have timely access to care, Provider shall follow the following standards set by DMHC and Accrediting Agency.

SERVICE	ACCESS TIME FRAME
Urgent Care Appointment PCP and Specialists  Services not requiring a prior Authorization  Services requiring a prior Authorization	<ul> <li>Within 48 hours of request for appointment</li> <li>Within 96 hours of request for appointment</li> </ul>
Non-urgent Appointment For the diagnosis or treatment of injury, illness, or other health condition. PCP and All Mental Health Providers  Specialist and Ancillary Services	Within 10 business days of request for appointment Within 15 business days of request for appointment
Preventative Care Appointment All Practitioners     Periodic follow-up     Standing referrals for chronic conditions     Pregnancy     Cardiac condition     Mental health conditions     Laboratory and radiology monitoring	May be scheduled in advance consistent with professionally recognized standards of practice as determined by the treating licensed healthcare Provider acting within the scope of his/her practice.
Telephone Triage or Screening All Practitioners	<ul> <li>Triage or screening waiting time does not exceed 30 minutes.</li> <li>Triage or screening must be available to Enrollees 24 hours per day, 7 days a week.</li> </ul>

- b. When it is necessary for a Practitioner or Member to reschedule an appointment, the appointment shall be promptly rescheduled in a manner that is appropriate for the Member's health care needs and ensures continuity of care consistent with professionally recognized standards of practice.
- c. The applicable waiting time for a particular appointment may be extended if the referring or treating licensed health care Provider, or the health care professional

providing triage or screening-services, as applicable, acting within the scope of his or her practice and, consistent with professionally recognized standards of practice; has determined and noted in the relevant records that a longer waiting time will not have a detrimental impact on the health of Member. (1300.67.2.2 (c)(5)(G))

#### II. <u>During and After Business Hours Services</u>

Provider shall employ an answering service or a telephone answering machine during and after business hours, which provide instructions regarding how Members may obtain urgent or emergent care including, when applicable, how to contact another Practitioner who has agreed to be on-call to triage or screen by phone, or if needed, deliver urgent or emergency care, and length of wait time for a return call from the Practitioner. (1300.67.2.2 (c)(8)(B)(1))

#### III. Timely Access Reporting

Provider shall work with Plan's Quality Management to develop a process for tracking and reporting timely access compliance. Provider shall provide a report of their findings to Plan on a quarterly basis if required.

### EXHIBIT H COVERED CALIFORNIA REQUIREMENTS

#### PROVIDER CONTRACT NAME

Provider shall comply with the following terms required by the QHP Contract. These provisions apply only to services provided to Covered California and Individual & Family Plan Members, collectively "Covered California Members".

#### 1. Compliance.

- a. Compliance Coordination. Provider shall coordinate and cooperate with Plan to the extent necessary to promote compliance by Plan and Provider with the applicable terms of the QHP Contract.
- b. Compliance with All Laws. Provider shall comply with all applicable federal, state, and local laws, regulations, executive orders, ordinances and guidance, including without limitation, the Affordable Care Act and the California Affordable Care Act; the Americans with Disabilities Act, the Anti-Kickback Statute, the Public Contracts Anti-Kickback Act, the Stark Law, and the Knox-Keene Health Care Service Plan Act of 1975, as applicable.
- 2. Independent Contractors. The Parties acknowledge and agree that, as required by 45 C.F.R. § 155.200(e), in carrying out its responsibilities, Covered California is not operating on behalf of Plan or Provider. In the performance of this Agreement, Plan and Provider shall always be acting and performing as an independent contractor, and nothing in the Provider Agreement shall be construed or deemed to create a relationship of employer and employee or partner or joint venture or principal and agent between or among Plan and Provider. Neither Plan, Provider, or any agents, officers or employees of any of them are agents, officers, employees, partners or associates of Covered California.
- 3. Disclosure of Financial Information. Provider agrees that Plan may disclose information relating to contracted rates between the Plan and Provider that is treated as confidential information by the DMHC pursuant to Health and Safety Code § 1385.07(b). Provider shall cooperate with Plan in providing Covered California with financial information relating to Provider that is (i) provided by Provider or Plan to the DMHC or other regulatory bodies, and (ii) reasonable and customary financial information that is prepared by Provider, including, supporting information relating to Covered California Members as required by Covered California. Possible requests may include (but not be limited to), annual audited financial statements, and annual profit and loss statements.

#### 4. Network Disruption.

a. Plan and Provider shall implement policies and practices designed (i) to reduce the potential for disruptions in Plan's Provider network, and (ii) to minimize the amount of uncertainty, disruption, and inconvenience of Covered California Members in the execution of the transition of care as required under state laws, rules and regulations in connection with any such disruption. Plan and Provider will maintain adequate

- records, reasonably satisfactory to Covered California, documenting its policies and its compliance with these requirements by Plan and Provider.
- b. In the event termination of the Agreement requires a block transfer of Covered California Members from Provider to a new Provider, Provider shall cooperate with Plan and Covered California in planning for the orderly transfer of Covered California Members as necessary and as required under applicable laws, rules, and regulations including but not limited to those relating to continuation of care set forth at Health and Safety Code § 1373.95.
- c. Provider shall notify Plan with respect to any material changes in its Provider network as of and throughout the term of this Agreement. For purposes of this Agreement, a material change in the disclosures shall relate to an event or other information that may reasonably impact Provider's ability to perform under this Agreement.

#### 5. Member Out-of-Network and Other Costs; Hold Harmless.

- a. Plan shall and shall require Providers to, comply with applicable laws, rules and regulations governing liability of Members for Covered Services provided to Members, including, those relating to holding a Member harmless from liability in the event Plan fails to pay an amount owing by Plan to a Provider as required by federal and state laws, rules and regulations.
- b. To the extent that Plan (i) provide coverage for out-of-network services and/or (ii) impose additional fees for such services, Plan shall disclose to the Member the amount it will pay for covered proposed non-emergent out-of-network services when requested by the Member.
- c. Plan shall require its Providers to inform every Member in a manner that allows the Member the opportunity to act upon that Provider's proposal or recommendation regarding (i) the use of a non-network Provider or facility or (ii) the referral of a Member to a non-network Provider or facility for proposed non-emergent Covered Services. Plan shall require Providers to disclose to the Member who is proposing or considering using out-of-network non-emergent services if a non-network Provider or facility will be used as part of the network Provider's plan of care. Plan's obligation for this provision can be met through an update to their Provider's contract manual that is effective as of January 1, 2014. Providers may rely on Plan's Provider directory as updated from time to time in fulfilling their obligation under this provision.

#### 6. Nondiscrimination.

a. In accordance with the Affordable Care Act § 1557 (42 U.S.C. 18116), Provider shall require as well as its agents and employees to refrain from causing an individual to be excluded from participation in, or to be denied the benefits of, or to be subjected to discrimination under, any health program or activity offered through Covered California on grounds prohibited under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), § 504 of

the Rehabilitation Act of 1973 (29 U.S.C. 794), or any other applicable state and federal laws.

b. Provider shall, as well as its agents, employees and sub-contractors to refrain from unlawful discrimination or harassment or from allowing harassment against any employee or applicant for employment because of sex, race, color, ancestry, religious creed, national origin, physical disability (including Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS)). mental disability, medical condition (including health impairments related to or associated with a diagnosis of cancer for which a person has been rehabilitated or cured), age (40 or over), marital status, genetic information, sexual orientation, gender identity or use of family and medical care leave. Participating Provider Group (PPG) shall and shall require its Sub-Subcontractors as well as their agents and employees to evaluate and treat employees and applicants for employment in a manner that is free from such discrimination and harassment. PPG shall and shall require its Sub-Subcontractors as well as their agents and employees to comply with the provisions of the Fair Employment and Housing Act (Government Code, Section 12900, et seq.) and the applicable regulations promulgated thereunder (2 CCR 7285.0, et seg.). The applicable regulations of the Fair Employment and Housing Commission implementing Government Code, Section 12990, set forth in CCR Chapter 5 of Division 4 of Title 2, including, 2, CCR Section 8103, et seq., are incorporated into this Agreement by reference and made a part hereof as if set forth in full. Provider shall give written notice of its obligations under this clause to labor organizations with which they have a collective bargaining or other agreement.

#### 7. Conflict of Interest; Integrity.

- a. Provider shall be free from any conflicts of interest with respect to Covered Services provided under this Agreement. Provider represents that Provider and its personnel do not currently have and will not have throughout the term of the Agreement, any direct or interest which may present a conflict in any manner with the performance of Covered Services required under this Agreement. Provider also represents that it is not aware of any conflicts of interest of any Sub-Subcontractors or any basis for potential violations of Provider with respect to laws, rules and regulations that govern referrals required for the provision of certain Covered Services to Covered California Members, including, federal and state anti-kickback and anti-self-referral laws, rules and regulations. Provider shall immediately (i) identify any conflict of interest that is identified during the term of the Agreement and (ii) take any necessary action to assure that any activities are not properly influenced by a conflict of interest.
- b. Provider shall comply with all applicable policies adopted by Covered California regarding conflicts of interest and ethical standards.
- **8. Customer Service.** Provider shall meet all state requirements for language assistance services that are applicable to Plan's Commercial HMO line of business.
- **9. Credentialing.** Plan shall perform, or may delegate activities related to, credentialing and re-credentialing in accordance with this Agreement. Plan agrees to maintain quality accreditation as outlined in this Agreement.

- **10. Other Laws.** Provider shall comply with applicable laws, rules and regulations, including the following:
  - a. Americans with Disabilities Act. Provider shall comply with the Americans With Disabilities Act (ADA) of 1990, (42 U.S.C. 12101, et seq.), which prohibits discrimination on the basis of disability, as well as all applicable regulations and guidelines issued pursuant to the ADA, unless specifically exempted.
  - b. Drug-Free Workplace. Provider shall comply with the requirements of the Drug-Free Workplace Act of 1990 (Government Code Section 8350, et seg.).
  - c. Child Support Compliance Act. Provider shall fully comply with all applicable state and federal laws relating to child and family support enforcement, including, but not limited to, disclosure of information and compliance with earnings assignment orders, as provided in Chapter 8 (commencing with Section 5200) of Part 5 of Division 9 of the Family Code.
  - d. Domestic Partners. Provider shall fully comply with Public Contract Code Section 10295.3 with regard to benefits for domestic partners.
  - e. Environmental. Provider shall comply with environmental laws, rules and Regulations applicable to its operations, including, those relating to certifies compliance with the requirements of the Electronic Waste Recycling Act of 2003, Chapter 8.5, Part 3 of Division 30, commencing with Section 42460 of the Public Resources Code, relating to hazardous and solid waste.
  - f. Other Laws. Provider shall comply with all other state and federal laws, rules and regulations applicable to this Agreement and Provider's provision of Covered Services under this Agreement.

### 11. Continuity of Care, coordination and cooperation upon termination of Agreement and transition of Members.

- a. Upon the termination of the Agreement, Provider shall fully cooperate with Plan or Covered California (the "Exchange") in order to affect an orderly transition of Members to another Provider or Certified QHP as directed by the Exchange. This cooperation shall include, without limitation, (i) attending post-termination meetings, (ii) providing or arranging for the provision of Covered Services as may be deemed necessary by Providers to assure the appropriate continuity of care, and/or (iii) communicating with affected Members in cooperation with the Exchange and/or the succeeding Provider, each as shall be reasonably requested by Covered California.
- b. In the event of the termination or expiration of the Agreement that requires the transfer of some or all Members into any other health plan, the terms of coverage under Plan's QHP Contract shall not be carried over to the replacement Qualified Health Plan (QHP) but rather the transferred Members shall be entitled only to the extent of coverage offered through the replacement QHP as of the effective date of transfer to the new QHP.

- c. Notwithstanding the foregoing, the coverage of Member under Plan's QHP Contract may be extended to the extent that a Member qualifies for an extension of benefits including, those to affect the continuity of care required due to hospitalization or disability pursuant to Health and Safety Code section 1373.96 et. seq. as amended.
- d. For purposes of this Agreement, "disability" means that the Member has been certified as being totally disabled by the Member's treating physician, and the certification is approved by Plan. Such certification must be submitted for approval within thirty (30) calendar days from the date coverage is terminated. Recertification of Member's disability status must be furnished by the treating Provider not less frequently than at sixty (60) calendar day intervals during the period that the extension of benefits is in effect. The extension of benefits shall be solely in connection with the condition causing total disability. This extension, which is contingent upon payment of the applicable premiums, shall be provided for the shortest of the following periods:
  - (i) Until total disability ceases;
  - (ii) For a maximum period of twelve (12) months after the date of termination, subject to plan maximums;
  - (iii) Until the Member's enrollment in a replacement plan; or
  - (iv) Recertification.

1 2 3 4 5 6 7 8 9 10	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200 Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS 199 Water Street, 22nd Floor New York, NY 10038 Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org  JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 105 West Adams, 26th Floor Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307 jgliksberg@lambdalegal.org	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837) MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL, COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl. San José, CA 95110-1770 Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org LEE H. RUBIN (SBN 141331) MAYER BROWN LLP Two Palo Alto Square, Suite 300 3000 El Camino Real Palo Alto, CA 94306-2112 Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com Counsel for Plaintiffs
10		
12 13	UNITED STATES I NORTHERN DISTRIC	
14	_	of Chemokini
15 16 17 18	COUNTY OF SANTA CLARA, TRUST WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS	Case No. 5:19-cv-2916  DECLARATION OF WARD CARPENTER, MD, CO-DIRECTOR OF HEALTH SERVICES, LA LGBT CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
19	FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN	
<ul><li>20</li><li>21</li></ul>	ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ	
22	EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER,	
23	SARAH HENN, and RANDY PUMPHREY,	
24	Plaintiffs,	
25	VS.	
26	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II,	
27	in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,	
28		
20	Defendants.	

I, Ward Carpenter, declare as follows:

- 1. I am the Co-Director of Health Services for the Los Angeles LGBT Center (LA LGBT Center), where I was formerly the Associate Chief Medical Officer as well as the Director of Primary and Transgender Care. I received my medical degree from the Robert Wood Johnson Medical School and had my residency at St. Vincent's Hospital Manhattan. I am board-certified in Internal Medicine and I hold certification in HIV Medicine. I am licensed to practice in the state of California. At the LA LGBT Center, I oversee all operations of the Federally Qualified Health Center ("FQHC"), including personnel, finances, clinical programs (mental health, psychiatry, primary care, HIV care, transgender health, substance abuse, and sexual health), nursing, case management, quality, risk management, and clinical research. I also maintain a panel of patients for whom I provide direct care. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction to prevent the Denial-of-Care Rule from going into effect.
- 2. As the Co-Director of Health Services, I oversee the healthcare of over 17,000 patients who come to the LA LGBT Center for their care; I personally provide care to a panel of 150 patients. All of my patients identify within the LGBTQ communities, and approximately 30% of my patients are people living with HIV. My patient population is also disproportionately low-income and experiences high rates of chronic medical conditions, homelessness, unstable housing, extensive trauma history, and discrimination and stigmatization in healthcare services. Many of these patients come to me from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.
- 3. I provide a wide spectrum of healthcare services, including, but not limited to, HIV treatment, testing and prevention; STD testing, treatment and prevention; general primary care with an LGBT focus; and comprehensive transgender care. I have worked in this field of medicine continuously since 2004 and have personally cared for over 4000 people in that time. I have worked in two Federally Qualified Health Centers, in New York and Los Angeles, as well as a private practice in New York. I am a nationally-recognized expert in the field of transgender medicine.
- 4. Many if not most of the individuals in our very diverse patient population face considerable stigma and discrimination as people living with HIV, as sexual or gender minority

people, as people of color. Transgender people have a 41% lifetime risk of attempting suicide. This shocking observation can be explained by the intense dysphoria inherent in living in a body and a society that does not reflect and validate who you know yourself to be at a core level. In order to avoid this tragic consequence, transgender people require compassionate, sensitive, and competent care that often includes medical and/or surgical procedures that incidentally affect reproduction. These patients have significantly improved mental health outcomes when able to proceed with the treatments they need. Treatments for gender dysphoria have been deemed medically necessary by the World Professional Association of Transgender Health and the Endocrine Society, in the same way that the American College of Cardiology has deemed treatment for hypertension medically necessary. In fact, in the course of treating gender dysphoria, endocrinologists and other healthcare providers use the same medications to treat transgender people as they use to treat non-transgender people with hormone deficiencies. Under the Denial-of-Care rule, medical personnel who are dutybound to treat someone for one condition – hypertension – could legally refuse to treat that same person for another condition – gender dysphoria – that could become life-threatening if left untreated despite having the necessary tools and expertise to do so. Healthcare discrimination like this will have immediate negative consequences for a distinct and oppressed minority group and cannot be empowered, as it is in the Denial-of-Care Rule.

5. There is every reason to believe that the Denial-of-Care Rule encourages healthcare providers and staff to claim an absolute right to refuse care or opt out of serving patients with particular needs, based on personal beliefs, and will result in more discrimination, mistreatment, and denials of healthcare services against LGBT patients and patients living with HIV at other clinics, doctors' offices, hospitals, pharmacies, and other healthcare facilities outside the LA LGBT Center. Even before the Denial-of-Care Rule was proposed or issued, I and the other providers that I supervise at the LA LGBT Center have had many patients who have experienced traumatic stigma and discrimination – based on their sexual orientation, gender identity, HIV status, and/or other factors. For example:

27

26

28

- a. A transgender patient went to a urologist due to uncomfortable urination lasting for several years after her vaginal surgery. She was repeatedly referred to as "sir" and "he" despite repeated requests to use the correct pronouns. When the patient confronted the clerk, the clerk said "this is what your ID says, so this is how we will refer to you." When she saw the doctor, he also called her "sir," completely humiliating her in the most unprofessional manner. He did not close the door to the exam room during their visit, so that the entire waiting room could hear his conversations with her, and he asked her to remove her pants in full view of the waiting room. She was so traumatized by this experience that four years later, she continues to live with daily pain rather than risk being subjected to discrimination by another transphobic urologist.
- b. A transgender patient started bleeding profusely from her vagina one week after surgery. Because there are so few trans-competent surgeons in the United States, this patient's surgeon was thousands of miles away. When she finally spoke to an ER doctor, the physician looked disgusted and said "what do you want me to do about it?" then walked away. She had to pack her own vagina with gauze pads and leave the ER, not knowing if she would live or die, and only coming to see us three days later after having lost a significant amount of blood. These horrific incidents will increase as a result of the Denial-of-Care Rule. The likely result: patients will die.
- c. A gay male patient with a serious and concerning neurological condition went to a neurologist. At this visit, the doctor had religious brochures throughout the waiting room. On arrival in the exam room, he was given a brochure about a particular Christian faith and asked if he had any questions. The patient felt extremely uncomfortable with this insertion of religion into what he felt should be a neutral space. As a result, he did not return for care

and experienced a delay of several more months trying to find a new doctor he could trust.

- d. A person living with HIV was referred to a surgeon for a routine procedure. The surgeon sent a note back to the patient's primary care physician asking him to refer the patient to someone "who was more familiar with treating patients like him." Again, this patient waited another two months to have this surgery, which could have caused severe or life-threatening complications.
- e. A lesbian woman went to her doctor and was told that lesbians are not at risk for HPV and, therefore, she did not need cervical cancer screening. This patient knew enough to find a new doctor, but many patients would accept this information as fact and never receive a Pap smear, significantly increasing their chances of dying from cervical cancer. This type of medical error based on discriminatory stereotypes demonstrates what will happen when medical personnel are invited to discriminate instead of focusing on the health needs of patients in their care.
- discharge. Because his healthcare provider did not ask, the provider did not know that this patient was sexually active with men. Therefore, the provider did only one test, which was negative, and sent him to a urologist. The urologist did another test, which was negative, then performed a procedure to look inside this man's bladder with a camera. It was not until he came to the LGBT Center that we performed a proper medical history and exam and were able to treat him immediately for his sexually transmitted infection. We also determined that he had sex with five other people from the time of his first symptoms to the time he was finally treated, weeks later. Had any of these providers stopped to ask the man about his sexual practices, they would have immediately tested him and treated him for a sexually

transmitted disease. Instead, he saw three providers, received hundreds of dollars in unnecessary testing and passed his infection along to five other people who themselves had to go down similar testing and treatment paths.

- 6. In sum, the message of these examples is clear: when patients are discriminated against, stereotyped, and mistreated in medical establishments as a result of healthcare providers' personal moral or religious beliefs, patients stop seeking care or their care is detrimentally delayed out of fear of repeated discrimination and denials of care. As a result, their conditions remain untreated for a much longer period of time, if they ever get treatment, resulting in much more acute conditions, ultimately costing the healthcare system millions of dollars in unnecessary expense while harming patients and public health. When medical staff fail to care for every patient in the best way that they can, putting patients' best interests at the center of medical care, medical mistrust is worsened, care is delayed, and healthcare becomes more expensive.
- 7. These incidents reveal that many healthcare providers and other staff harbor explicit or implicit biases against LGBT people and people living with HIV. Because of legal requirements, healthcare facility non-discrimination policies, and professional norms, many of them have kept their personal beliefs and feelings in check. By empowering healthcare staff to think that they have the right to act on their personal beliefs, even at the expense of patient needs, the Denial-of-Care Rule is very likely to result in many more incidents of discrimination and greater harm to LGBT individuals and patients living with HIV who are struggling with mental health or substance use issues, including the patients whom I treat and whose treatment I supervise.
- 8. Such experiences are not only insulting and demoralizing for the patient, but can jeopardize the patient's health, when a screening or treatment is denied or postponed, or the patient is discouraged from seeking medical care out of fear of repeated discrimination. Many if not most of my and the LA LGBT Center's transgender patients express strong distrust of the healthcare system generally, and a demonstrative reluctance to seek care outside the LA LGBT Center unless they are in a crisis or in physical or mental stress. This is because they want to avoid discrimination or belittlement. Such incentives to avoid regular check-ups and other medical care can result in

disease processes that are more advanced at diagnosis, less responsive to treatment, or even no longer curable in the case of some cancers. Already, my patients are arriving at the LA LGBT Center with more acute medical conditions than they would otherwise have because the increase in religious-based discrimination has caused patients to fear receiving necessary medical care.

9. With existing health and healthcare disparities that harm the LGBTQ community – particularly the shortage of LGBTQ/HIV culturally competent providers – the Denial-of-Care Rule's vague and confusing language will further exacerbate existing barriers to healthcare and result in negative community health outcomes. Good medical care is based on trust as well as frank and full communication between the patient and their provider. In many, if not most encounters, providers need patients to fully disclose all aspects of their health history, sexual history, substanceuse history, lifestyle, and gender identity in order to provide appropriate care for the patients' health, both physical and mental. Incomplete communication, or miscommunication, can have dangerous consequences. For instance, a patient who conceals or fails to disclose a same-sex sexual history may not be screened for HIV or other relevant infections or cancers; and a patient who fails to fully disclose their gender identity and sex assigned at birth may not undergo medically-indicated tests or screenings (such as tests for cervical or breast cancer for some transgender men, or testicular or prostate cancer for some transgender women). Patients need to be encouraged to fully disclose all information relevant to their healthcare and potential treatment, which can only be achieved when patients are assured that the information they provide will be treated confidentially and with respect. The Denial-of-Care Rule endangers the provider-patient relationship, and is likely to harm many patients' health, by discouraging patients from full disclosure, and by encouraging providers to avoid topics that may offend their personal moral or religious beliefs in their encounters with patients.

10. The Denial-of-Care Rule causes LGBT patients and patients living with HIV to lose trust in their healthcare providers (either out of fear of discrimination or on account of being denied care on religious grounds). As a result, there will be an increase in demand for my and my department's services that will limit my ability to provide adequate care and time to my patients.

28

25

26

27

This will increase wait times for my patients, and the delays in care may worsen conditions for which my patients are seeking treatment and outcomes of care.

- 11. The Rule will cause LGBT patients to attempt to hide their LGBT identities when seeking healthcare services, especially from religiously-affiliated healthcare organizations, in order to avoid discrimination. The Denial-of-Care Rule endangers the provider-patient relationship, and is likely to harm many patients' health, by discouraging patients from full disclosure about their gender identity, sexual orientation, or medical histories. Patients will avoid raising any topics, questions, facts that they fear could possibly offend their healthcare providers' personal beliefs, resulting in harm to patients. When patients are unwilling to disclose their sexual orientation and/or gender identity to healthcare providers out of fear of discrimination and being refused treatment, their mental and physical health is critically compromised.
- 12. The Denial-of-Care Rule is also likely to cause an increase in demand for my healthcare services because I have seen a spike in behavioral and mental-health issues resulting from religious or moral-based discrimination and denials of healthcare services.
- 13. The Denial-of-Care Rule is in direct conflict with the oath I swore as a doctor and many of the federal, state, and insurance rules, regulations, and statutes that I am required to follow. This has personally caused me great confusion and stress as it is unclear how I can work collaboratively with colleagues who may discriminate against my patients without violating either current medical ethical and legal standards of care or the Denial-of-Care Rule.
- 14. As a healthcare provider with the LA LGBT Center, I receive various forms of federal funding directly and indirectly via federal programs, including but not limited to those governed by the Centers for Medicare and Medicaid Services through Medicaid and Medicare reimbursements as well as funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 and funding from the Centers for Disease Control and Prevention. These funds and related benefits account for a significant portion of my work and the healthcare services that I, and those that I supervise, provide to patients. Without such funding, we could not provide proper treatment to our patients, especially because a large portion of the population that we serve relies heavily on Medicaid and Medicare for its healthcare needs. I may be, therefore, subject to

16 17 18

20 21

22

23

24

25 26

27 28

the restrictions of HHS's Denial-of-Care Rule and have a reasonable fear that I could be sanctioned and lose federal funding for the work that I do as a result of nondiscrimination policies that I enforce in my department and amongst the staff that I supervise, which is vital to providing proper care to my patients and other patients whose care I supervise. If such a loss of funding were to occur, it would result in service reductions if not closure of our programs in their entirety.

15. One of the guiding ethics of medicine is to treat all patients equally. We do not treat blue-eyed people better than brown-eyed people. We do not treat women better than men. We do not provide better care to blonde-haired people than red-haired people. Medical personnel see people at their most vulnerable; the trust placed in us is sacred. To tie an employer's hands, to not permit an employer to make respectful and equal treatment of all patients part of a job description, hurts patients by preventing them from accessing needed care even at trusted facilities and practices. If we at the LA LGBT Center need to provide care to the LGBT community, we cannot be forced to hire and continue working with someone who refuses to provide care to this community without violating the LA LGBT Center's mission, medical ethics, and established standards of care.

16. As LA LGBT Center's Co-Director of Health services, my responsibility includes enforcing our nondiscrimination mandate with respect to all of our providers and staff, including those working on federally funded research. I, therefore, have a reasonable fear that the ability to provide federally funded healthcare services and conduct federally funded research could be severely impeded, potentially putting patients and research participants at risk, if the Denial-of-Care Rule is allowed to take effect. I could also be subject to sanctions as someone who oversees the LA LGBT Center's clinical research.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 6, 2019

Respectfully submitted.

Ward Carpenter

2 3 4 5 6 7 8 9 10	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200 Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS 199 Water Street, 22nd Floor New York, NY 10038 Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org  JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 105 West Adams, 26th Floor Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307 jgliksberg@lambdalegal.org	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837) MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL, COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl. San José, CA 95110-1770 Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org  LEE H. RUBIN (SBN 141331) MAYER BROWN LLP Two Palo Alto Square, Suite 300 3000 El Camino Real Palo Alto, CA 94306-2112 Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com  Counsel for Plaintiffs
12	UNITED STATES I	NISTRICT COURT
13	NORTHERN DISTRIC	
14	COUNTY OF SANTA CLARA, TRUST	No. 19-cv-2916 NC
15	WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC,	
16	INC. d/b/a WHITMAN-WALKER HEALTH,	DECLARATION OF SARA H. CODY, M.D., HEALTH OFFICER AND
17	BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON	DIRECTOR OF COUNTY OF SANTA CLARA PUBLIC HEALTH
	HALSTED, HARTFORD GYN CENTER,	
18		DEPARTMENT, IN SUPPORT OF
18 19	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION	DEPARTMENT, IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR	PLAINTIFFS' MOTION FOR
19	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH	PLAINTIFFS' MOTION FOR
19 20 21	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS,	PLAINTIFFS' MOTION FOR
19 20 21 22	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ	PLAINTIFFS' MOTION FOR
19 20 21 22 23	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER,	PLAINTIFFS' MOTION FOR
19 20 21 22 23 24	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,	PLAINTIFFS' MOTION FOR
19 20 21 22 23 24 25	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,  Plaintiffs,  vs.  U.S. DEPARTMENT OF HEALTH AND	PLAINTIFFS' MOTION FOR
19 20 21 22 23 24 25 26	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,  Plaintiffs,  vs.  U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF	PLAINTIFFS' MOTION FOR
19 20 21 22 23 24 25	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,  Plaintiffs,  vs.  U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II,	PLAINTIFFS' MOTION FOR

#### I, SARA H. CODY, M.D., declare as follows:

- 1. I am a resident of the State of California. I submit this declaration in support of the County of Santa Clara's ("County"), and its co-plaintiffs', Motion for Preliminary Injunction. I have personal knowledge of the facts set forth in this declaration. If called as a witness, I could and would testify competently to the matters set forth herein.
- 2. I am the Director of the County's Public Health Department, as well as the Health Officer for the County and each of the 15 cities located within Santa Clara County. I have held the Health Officer position from 2013 to the present and have held the Public Health Department Director position from 2015 to the present. In these roles, I provide leadership on public health issues for all of Santa Clara County and oversee approximately 450 Public Health Department employees, who provide a wide array of services to safeguard and promote the health of the community.
- 3. Prior to becoming the Health Officer for the County and each of its cities, I was employed for 15 years as a Deputy Health Officer/Communicable Disease Controller at the County's Public Health Department, where I oversaw surveillance and investigation of individual cases of communicable diseases, investigated disease outbreaks, participated in planning for public health emergencies, and responded to Severe Acute Respiratory Syndrome (SARS), influenza A virus subtype H1N1 (also known as "swine flu" or H1N1), and other public health emergencies.
- 4. The mission of the Public Health Department is to promote and protect the health of Santa Clara County's entire population. None of Santa Clara County's 15 cities have a health department. All 15 cities, and all Santa Clara County residents, rely on the Public Health Department to perform essential public health functions. The Public Health Department's work is guided by core public health principles of equity, the value of every life, and harm prevention. The Public Health Department's direct services primarily benefit low-income persons, children, people of color, and people living with chronic diseases, such as HIV/AIDS.

- 5. The work of the Public Health Department is focused on three main areas: (1) infectious disease and emergency response, (2) maternal, child, and family health, and (3) healthy communities.
- 6. The Public Health Department provides care focused on some of the County's most vulnerable populations including, but not limited to, the LGBTQ community, low-income residents, people who abuse controlled substances, and young women who are pregnant.

  Approximately 25% of the County's nearly two million residents are considered to be among these vulnerable populations. It is critical that Public Health Department staff be willing and able to serve these populations. For that reason, in recruitment for employment in the Public Health Department, the County inquires into job applicants' experiences with the LGBTQ community and with other vulnerable populations. This recruitment practice ensures that our Department is staffed with employees who are prepared to serve, and are experienced with serving, the needs of all County residents who may interact with the Public Health Department.
- 7. Several specific programs would be undermined if the Public Health Department were prevented from ensuring that employees staffing those programs were willing to provide the health care services required. For example, the Public Health Department operates a needle exchange program that is critical to preventing the spread blood-borne pathogens such as HIV, hepatitis B and hepatitis C, and also helps to address substance abuse in Santa Clara County. County employees participating in this program necessarily interact with people who abuse controlled substances and typically engage in services such as providing clean needles, safer-sex kits, and referrals for substance abuse treatment. If the Department could not ensure that employees staffed on the needle exchange program are willing to provide these services, the program would not be able to operate efficiently or effectively. Similarly, if the Department could not reassign an employee who objected to providing such services, we would not be able to staff appropriately, undermining this critical program.
- 8. The Public Health Department provides a range of STI-related services, including sexual-health counseling, STI-prevention services, STI screening, STI treatment, and HIV pre-

exposure and post-exposure prophylaxis. Through both the Crane Center, which focuses on STI screening for HIV and Hepatitis C, and the STI clinic, which provides examinations and treatment for a wide range of STIs, such as syphilis, gonorrhea and chlamydia, the Public Health Department regularly serves the LGBTQ community, women who are pregnant including those who may be considering abortion, and people who are seeking contraceptive care. If a broad swath of Public Health employees—even those not directly providing patient care—could refuse to facilitate or refer patients for certain care based on religious or moral objections, these programs would be dramatically impacted. Such refusals would interfere with the relationship of trust between our providers and our patients and result in situations where patients seeking care are turned away or provided with incomplete information regarding the health care services available.

- 9. A policy that broadly permits employees to refuse to facilitate patient care could have a serious negative impact on public health. Indeed, STIs are already a serious public health concern in Santa Clara County, which has recently experienced a rise in chlamydia, gonorrhea, and syphilis. Between 2010 and 2017, cases of chlamydia steadily increased from 271.3 cases per 100,000 people in 2010 to 392.7 cases in 2017, and gonorrhea rates increased nearly fourfold from 33.1 cases per 100,000 people in 2010 to 126.4 cases in 2017, with a 26% rapid increase from 2016 to 2017. Rates of early syphilis (i.e., primary, secondary, and early latent syphilis) diagnoses nearly tripled from 6.2 cases per 100,000 people in 2010 to 21.1 cases in 2017, with a sharp 57% increase between 2015 and 2016. HIV/AIDS is another serious public health concern in the County. In 2015, there were 2,734 people living with HIV/AIDS in the County, and in 2017, that number had risen to 3,361 people living with HIV/AIDS in the County. Any requirements that obstruct patient access to treatment are likely to exacerbate these serious public health problems and thus increase the burden on the County to address and prevent the spread of these infections.
- 10. Public Health's STD/HIV Prevention and Control program distributes free condoms at its clinical sites and through outreach events to the community. If Public Health were

unable to require advance notice of religious objections or reassign objecting employees, an employee who has a religious objection to contraceptives or premarital sex could refuse to participate in and seriously undermine this program. Decreased access to, and education about, contraception is likely to increase unintended pregnancies, triggering immediate and long-term costs to the County and communities nationwide. As the safety-net healthcare provider, the County funds many of the medical services associated with preventing and treating both STIs and unintended pregnancies, which disproportionately affect young, low-income, minority women, without access to higher education, who are likely to rely on County-funded services. The County is also burdened by the long-term costs of unplanned pregnancies, which can limit individuals' ability to succeed in education and the workplace and to contribute as taxpayers and citizens.

- 11. The Public Health Department depends heavily upon federal funding from the U.S. Department of Health and Human Services. The elimination of this federal funding would be devastating for the residents of Santa Clara County. It would result in a drastic reduction of services and staff positions in Public Health Department programs providing direct services to clients, as well as other programs integral to protecting and promoting public health. Vulnerable communities would be most severely impacted by a loss of federal funding to the Public Health Department.
- 12. In the County's 2017-18 fiscal year, from July 1, 2017 through June 30, 2018, the Public Health Department's total gross expenditures amounted to approximately \$102 million. Total revenues from federal funds in the 2017-18 fiscal year amounted to approximately \$36 million, or more than a third of the Department's gross expenditures. Most of these federal funds pass through the State of California to the County.
- 13. Federal funding is critical to many of the Public Health Department's programs that address infectious diseases. The Public Health Department is responsible for safeguarding the public health by preventing and controlling the spread of infectious diseases and planning for and responding to public health emergencies. Programs in this branch of the Public Health

Department receive reports on 85 different diseases and conditions; track overall trends in infectious diseases; investigate individual cases of concern; provide long-term case management for certain categories of patients (e.g., active tuberculosis cases); provide immunizations and preventive therapy; identify, investigate and control outbreaks; and plan for and respond to public health emergencies. They also ensure that all children attending school or childcare facilities in Santa Clara County comply with State immunization requirements; conduct HIV and other STI testing and education for vulnerable communities; and distribute opioid overdose prevention kits for at-risk individuals. To support its communicable disease control function, the Public Health Department has a public health laboratory, which serves as a local and regional resource which local health providers, clinics, hospitals, and even law enforcement rely on to test and identify infectious diseases, toxins, biohazards, and other substances that could pose a serious risk to public health. This branch of the Public Health Department also includes two pharmacies.

- 14. For example, in Fiscal Year 2015-2016, Public Health Department programs supported by federal funding included the following:
- a. Under the federal government's Ryan White HIV/AIDS Program, the County received \$4.0 million in funds to provide core medical services and support services to low-income individuals living with HIV/AIDS in the County. In calendar year 2016, there were 1,267 Ryan White-funded clients in Santa Clara County—nearly half of all the persons living with HIV/AIDS in Santa Clara County.
- b. The County received approximately \$2 million for drugs provided to uninsured and underinsured HIV/AIDS patients enrolled in the AIDS Drug Assistance Program. These are patients who are at or below 500% of the Federal Poverty Level and do not qualify for no-cost Medi-Cal. The majority of this \$2 million consists of federal funds, with state funds comprising the remainder.
- c. Through the National Hospital Preparedness Program and Public Health Emergency Preparedness Cooperative Agreement Programs, the Public Health Department has

received \$2.6 million in federal funding to prepare for emergencies, such as natural disasters, mass casualties, biological and chemical threats, radiation emergencies and terrorist attacks.

- 15. Further, in the area of maternal, child, and family health, the Public Health Department provides services for Santa Clara County's most vulnerable children and families.
  The following are some of the Public Health Department's federally funded programs in this area:
- a. The California Children's Services (CCS) program provides diagnostic and treatment services, medical case management, and medically necessary physical and occupational therapy services to children under 21 years of age with CCS-eligible medical conditions, such as cystic fibrosis, hemophilia, cerebral palsy, muscular dystrophy, spina bifida, heart disease, cancer, and traumatic injuries. The CCS program serves well over 5,000 children each year, and in Fiscal Year 2015-2016, it received \$4.9 million in federal funds, not including payments from Medi-Cal.
- b. The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) program safeguards the health of low-income pregnant, postpartum, and breastfeeding women, infants, and children up to age 5 who are at nutritional risk by providing nutritious foods to supplement diets, information on healthy eating, breastfeeding promotion and support, and referrals to health care. The program has a caseload of nearly 16,000 individuals each month, and it received \$4.1 million in federal funds in Fiscal Year 2015-2016.
- c. The Child Health and Disability Prevention (CHDP) Program, which received \$1.6 million in federal funds in Fiscal Year 2015-2016, ensures that low-income children and youth receive routine health assessments and treatment services. Within the CHDP Program, public health nurses also provide case management for foster care youth to ensure that their medical, dental, mental health, and developmental needs are met.
- d. The Public Health Nursing Home Visitation program, which received \$1.3 million in federal funds (Targeted case management) in Fiscal Year 2015-2016, provides case management services to Medi-Cal beneficiaries in specific target populations to gain access to needed medical, social educational, and other services.

- e. The Childhood Lead Poisoning Prevention Program, which received approximately \$88,000 in federal funds in Fiscal Year 2015-2016, provides nursing and environmental case management and follow-up for lead-poisoned children, promotes screening for lead poisoning, and provides community education regarding lead poisoning prevention.
- 16. To create and maintain healthy communities, the Department conducts localized health assessments and planning throughout Santa Clara County, and works with community partners and County leadership to promote system-wide and environmental changes to reduce the incidence of chronic diseases and injuries in Santa Clara County. In Fiscal Year 2015-2016, the chronic disease and injury prevention unit received \$1.6 million in federal funds to provide nutrition education and obesity prevention activities and interventions for low-income Californians for primary prevention of nutrition-related chronic disease.
- 17. In addition to the programs described above, the Public Health Department received \$6.1 million in Medi-Cal payments and \$2.4 million in Medicare payments in Fiscal Year 2015-2016 for health care provided to patients with Medi-Cal or Medicare coverage. The payments from Medicare, which is the federal health insurance program for elderly and disabled individuals, consist entirely of federal funds. Medi-Cal is financed by the State and federal governments, and the Medi- Cal payments therefore contain a mixture of State and federal funds. Although the apportionment of the funding is not readily known to the County, the Medi-Cal payments are dependent on receipt of federal funding from Medicaid, the federal health insurance program for low-income individuals.
- 18. The Public Health Department continues to receive comparable federal funding from the U.S. Department of Health and Human Services annually. Given increases in the population of the County, the Public Health Department likely relies on a slightly higher total amount of federal funding now than in Fiscal Year 2015-16.
- 19. Many, if not most, of the individuals served through the Public Health
  Department's various programs simply would not get the care and resources that they need
  without federally funded services. For example, without federal funding for WIC, thousands

more women would not have the appropriate nutrition to ensure healthy pregnancies, healthy birth outcomes, and healthy children, and thousands more children would suffer from poor nutrition. This would impact not only their immediate health but also their developmental readiness for kindergarten and chances for future health and success in life. As another example, loss of funding for CCS would result in reduced therapy and other necessary services for thousands of medically fragile and disabled children with expensive and complicated medical conditions. And as yet another example, loss of funding for clients with HIV/AIDS would mean that hundreds of low-income, chronically ill individuals in our community would not receive the health care, drugs, and other essential services they need to survive and enjoy a reasonable quality of life. Patients with HIV infection who are not adequately treated are also at greater risk of spreading HIV to others. The fees the STI clinic collects do not cover the costs of providing STI-related services, and if the Department's budget loses federal funding, we would not be able to continue with the same level of services going forward.

traditionally funded by federal dollars. A withdrawal of federal funding for the County would require a countywide realignment of funding and priorities, and money that is currently allocated to the Public Health Department from the County's General Fund could be reduced to make up for a loss of federal funds in other departments. A loss of federal funding, combined with a reduction in the General Fund allocation for the Public Health Department, would require the Public Health Department to make difficult decisions about how to reallocate its remaining funds, which communities to prioritize, and which diseases and health conditions to focus on at the expense of others. Rather than being in a position to create and implement proactive strategies to promote health and prevent disease, the Public Health Department would almost certainly be forced into focusing on reactive services designed to address public health crises (e.g., communicable disease control), services that the Public Health Department and Health Officer are mandated by law to provide (e.g., birth and death registration), and a modicum of services for the neediest populations.

- 21. A withdrawal of federal funding would compromise the Public Health
  Department's ability to prevent public health emergencies and outbreaks, to prevent chronic
  diseases, to provide equal opportunity to vulnerable children for a healthy start and optimal
  health, and to foster healthy families and healthy communities.
- 22. A sustained loss of federal funding to the County would ultimately result in a far sicker and less healthy community overall and for generations to come. The collateral costs would be many: greater health care costs for individuals, their families, their employers, and for the County itself, which is mandated by law to provide health care to the medically indigent. In addition, I am familiar with a wide body of studies and literature showing that an increase in incidents of sickness and illness can result in financial instability for families, a less productive workforce, and poorer educational and economic outcomes for children.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 5, 2019

Respectfully submitted,

SARA H. CODY, M.D.

1 2 3 4 5 6 7 8 9 10	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200 Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS 199 Water Street, 22nd Floor New York, NY 10038 Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org  JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 105 West Adams, 26th Floor Chicago, IL 60603-6208 Tel: (312) 663-4413; Fax: (312) 663-4307 jgliksberg@lambdalegal.org	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837) MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL, COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl. San José, CA 95110-1770 Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org LEE H. RUBIN (SBN 141331) MAYER BROWN LLP Two Palo Alto Square, Suite 300 3000 El Camino Real Palo Alto, CA 94306-2112 Tel: (650) 331-2000; Fax: (650) 331-2060 lrubin@mayerbrown.com  Counsel for Plaintiffs
12		
13	UNITED STATES I NORTHERN DISTRIC	
14	COUNTY OF SANTA CLARA, TRUST	Case No. 5:19-cv-2916
15	WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC,	
16	INC. d/b/a WHITMAN-WALKER HEALTH,	DECLARATION OF DARREL CUMMINGS, CHIEF OF STAFF OF
17	BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON	THE LOS ANGELES LGBT CENTER,
18	HALSTED, HARTFORD GYN CENTER,	IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY
	MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION	INJUNCTION
19	OF LGBTQ+ PSYCHIATRISTS, AMERICAN	
20	ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH	
21	PROFESSIONALS ADVANCING LGBTQ	
22	EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER,	
23	SARAH HENN, and RANDY PUMPHREY,	
24	Plaintiffs,	
	vs.	
25	U.S. DEPARTMENT OF HEALTH AND	
26	HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF	
27	HEALTH AND HUMAN SERVICES,	
28	Defendants.	

I, Darrel Cummings, hereby state as follows:

- 1. I am currently the Chief of Staff of the Los Angeles LGBT Center ("the Center"), a not-for-profit 501(c)(3) organization based in Los Angeles, California, that provides a variety of services to members of the lesbian, gay, bisexual, and transgender ("LGBT") communities. I have served in that capacity since 2003, and also previously served as Chief of Staff from 1993 through 1999. More broadly, I have been an advocate on LGBT issues since 1979. I am submitting this Declaration in support of Plaintiffs' motion for a preliminary injunction to prevent the Denial-of-Care Rule from taking effect.
- 2. The Center was founded in 1969 and offers programs, services, and global advocacy that span four broad categories: health, social services and housing, culture and education, and leadership and advocacy. The mission of the Center is to fight bigotry and build a world where LGBT people thrive as healthy, equal, and complete members of society. Today the Center's more than 650 employees provide services for more LGBT people than any other organization in the world, with about 500,000 client visits per year.
- 3. As the largest provider of services to LGBT people in the world, many of the Center's patients tell us that they come to the Center seeking culturally competent healthcare due to being denied care or discriminated against based on their real or perceived sexual orientation, gender identity and HIV status. The Center's client population is disproportionately low-income and experiences high rates of chronic physical and mental conditions, homelessness, unstable housing, trauma and discrimination, and stigmatization in healthcare services. Many of these clients come to the Center from different areas of California, other states, and even other nations to seek services in a safe and affirming environment.
- 4. The Center is one of the nation's largest and most experienced providers of LGBT health and mental healthcare. We accept a variety of health insurance plans, including Medi-Cal

(California's Medicaid program), Medicare, and most private insurance plans. We also provide services to uninsured individuals. We work with these individuals to help them access insurance through Covered California (California's Affordable Care Act "exchange"), and/or navigate other medical- and drug-assistance programs. Where insurance is not available, our services are offered on a sliding-scale basis, based on ability to pay. We pride ourselves on providing leading-edge healthcare, regardless of individuals' ability to pay.

- 5. The Center receives various forms of Health and Human Services funding, including Public Health Service Act funding. Approximately 80 percent of the Center's funding originates from the federal government, including, but not limited to, funding under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, direct funding from the Centers for Disease Control and Prevention, discounts under the 340B Drug Discount Program, and Medicaid and Medicare reimbursements. The Center also receives federal funding for research programs, and is currently a participant in multiple federally-funded studies, including through National Heart, Lung, and Blood Institute; National Institute of Allergy and Infectious Diseases; National Institute of Child Health and Human Development; the National Institutes of Health, National Institute of Drug Abuse, and the Patient-Centered Outcomes Research Institute. The Center is, therefore, subject to the substantive requirements of the Denial-of-Care Rule and has a reasonable fear that it could be at risk of sanction and loss of federal funding as a result of the Denial-of-Care Rule.
- 6. As a federally qualified health center, the Center is required to serve anyone on a nondiscriminatory basis who walks into its doors. The Denial-of-Care Rule's vague language makes it difficult for the Center to decipher how to proceed in light of contradictions between the Denial-of-Care Rule on the one hand and, on the other hand, nondiscrimination requirements, medical statutes, rules, standards of care, ethics requirements, and accreditation standards. The Denial-of-Care Rule invites chaos within the Center, will consume the Center's resources, and will

make it more difficult for the Center to provide the same level of premier care to its patients. The Center cannot function in such an environment.

- 7. The Center provides a wide spectrum of healthcare services, including, but not limited to, HIV treatment, testing, and prevention care, as well as treatment for gender dysphoria and mental healthcare. The Center has medical providers who specialize in the care of transgender patients and who provide a full range of primary care services in addition to hormone therapy, preand post-surgical care, and trans-sensitive pap smears, pelvic exams, and prostate exams. The Center's broad array of healthcare services are all under one roof, from counseling and therapy to pharmaceutical and nutrition needs.
- 8. The Denial-of-Care Rule will worsen health disparities between the LGBT community and other communities. With existing health and healthcare disparities in the LGBT community particularly the shortage of LGBT/HIV culturally competent providers the Denial-of-Care Rule's broad and vague language and invitation to providers to engage in discrimination will further exacerbate existing barriers to healthcare and result in negative community health outcomes.
- 9. For example, the Center's providers have observed patients arriving at the Center with acute medical conditions that could have been avoided but-for the patients' reluctance to seek routine and necessary medical care for fear of discrimination and being turned away. A shocking number of LGBT patients fear going to a healthcare provider due to negative past experiences directly related to their sexual orientation or gender identity. The Denial-of-Care Rule will exacerbate those numbers as a result of increased discrimination and denials of healthcare treatment. For similar reasons, LGBT people are less likely to have a primary care provider whom they consider their personal doctor. That means that in times of need, LGBT people are more likely to randomly select a healthcare provider with whom they do not have a relationship, and they are at increased risk of finding a provider who is not LGBT-affirming. With an increase in refusals of

healthcare services as a result of the Denial-of-Care Rule, LGBT people will be far less likely to receive the healthcare treatment that they need because, after being turned away, they are unlikely to seek other care out of fear of repeated rejections.

10. This directly affects the Center because there will be an increase in community members seeking referrals to LGBT-affirming services that the Center does not have sufficient resources to provide, an increase in community members experiencing the trauma of discriminatory or unwelcoming healthcare experiences, and worsened community health outcomes among the population that the Center serves. Additionally, the Center will have to expend more resources on its health promotion campaigns to ensure that LGBT patients access necessary preventative screenings and testing (including for cancer, HIV and other STIs) given that the Denial-of-Care Rule will change the healthcare landscape for the LGBT patient population.

11. For some patients that the Center serves, especially those who live in regions with limited options for LGBT-affirming healthcare services, finding LGBT-inclusive healthcare options is already a struggle. Additionally, for some medical specialties, there are only a handful of healthcare providers in a patient's region who have the specialty necessary to treat the patient, so a denial of care by even one provider could make it practically impossible for an LGBT patient to receive the specific healthcare service sought. This is even more concerning in regions where patients' only options are religiously-affiliated organizations that could claim religious or moral-based objections to providing any and all care to LGBT patients as a result of the Denial-of-Care Rule, in contradiction to medical ethics and standards of care.

12. The Denial-of-Care Rule's overly broad language invites increased discrimination against LGBT people and people living with HIV at other healthcare centers, outside of the Center. The Center's healthcare providers – particularly its counselors, psychiatrists and other behavioral-health staff – have treated many patients who have experienced traumatic stigma and discrimination

based on sexual orientation, gender identity, HIV status, and/or other factors. The stories that patients tell the Center's staff about their discriminatory experiences outside of the Center include:

- a. One transgender patient was unable to find supportive mental-health housing due to discriminatory experiences based on gender identity, which led to the patient being homeless.
- b. Another transgender patient, who developed profuse bleeding after surgery, was denied treatment at an emergency room where they were told by an emergency room doctor: "what do you want me to do about it?" They arrived at the Center in distress three days later, having lost a significant amount of blood.
- c. A transgender patient needed to have a pelvic exam. The Center referred him to a specialist who denied services to him because he was transgender.
- d. Patients have stated that their physicians told them that they do not need HIV testing because they are not engaging in same-sex sexual relationships. Not only is that conclusion contrary to medical guidelines, but when patients refuted assumptions about their sexual relationships, they were met with disapproval.
- e. Patients have expressed concern about traveling outside of Los Angeles for business because if they are ever in need of emergency medical assistance, they will not know where to go to ensure that they will receive nondiscriminatory, proper healthcare services.
- f. One patient recalled that when her late partner was in the hospital, she was there most of the time to care for her. There was a nurse who treated them kindly and appropriately until the nurse heard them refer to each other by

"Honey." The look on the nurse's face changed and she treated the couple "like trash" after that. The patient remarked that allowing healthcare employees (everyone from those working in food service and housekeeping to physicians and nurses) to express their religious or moral views when providing care to patients results in placing LGBT patients in a "lesser-than" category of patients.

- g. Patients residing at assisted-living facilities have described discrimination and denials of care when their sexual orientation, gender identities, and HIV statuses were revealed. Patients who are transgender have described having to hide their gender identities and transgender status once they are no longer able to care for themselves and are required to find assisted-living arrangements.
- h. Patients have described being intentionally referred to by names and pronouns other than their preferred names while seeking healthcare services elsewhere.
- i. A patient described being given his positive HIV results by way of his provider placing a lab printout on the counter then leaving for 10 minutes and letting the patient read it. The patient was not given any further information, and was instead told to go to our Center.
- j. Patients have reported that their primary care physicians do not feel comfortable prescribing HIV preventatives, such as Truvada for PrEP, even when such medications are appropriate and should be provided according to current medical guidelines and standards of care. Patients also have reported that their physicians shame them for requesting PrEP medications and then

deny them the medication, which is how they find their way to the Center. For example, when one patient asked his provider about Truvada, his physician questioned him as to why he needed it and proceeded to tell the patient that he would not need the medication if he were more careful. Another patient was denied PrEP altogether and lectured that he did not need PrEP unless he was having sex with sex workers.

- k. Patients also have expressed reluctance to use their insurance for PrEP because they are afraid of having the drug documented on their insurance record. These patients fear that a history of using a medically necessary HIV preventative could be used against them in the future by making them targets for discrimination based on sexual orientation, gender identity and/or transgender status, and HIV status, given the current political climate and discrimination in the healthcare context.
- A significant number of patients come to the Center's Sexual Health and Education Program for testing and sexual education rather than their primary care physicians because they do not feel comfortable talking about their sexual histories and choices out of fear of being treated negatively, judgmentally, and with bias and discrimination.
- m. Multiple patients have stated that they come to the Center to be tested for sexually transmitted infections because the Center does rectal and throat swabs instead of only urine tests. Not all healthcare providers do all three forms of testing even though three-site testing provides the most accurate results for testing and treating sexually transmitted infections. This is especially true for gay men. Someone could test negative for a sexually

transmitted infection with a urine test, for example, but test positive with a rectal swab. Patients report that when they specifically asked their outside provider to do rectal swabs, they were judged. When patients are judged by their physicians and/or cannot be out to their physicians about their sexual orientation and/or gender identity out of fear of discrimination, LGBT patients cannot receive the healthcare services that they need, including prophylactic treatments, and may experience delays in medically necessary treatments, resulting in more acute, life-threatening conditions.

13. Many of the Center's patients and LGBT people in general have reported that they are not out to their other medical providers about their sexual orientation and/or gender identities out of fear of discrimination and denial of healthcare. The discriminatory mischaracterization of transgender-affirming care as "sterilization" in the preamble to the Denial-of-Care Rule will result in an increase in the examples of discrimination cited above. For many transgender individuals, gender confirmation surgery is a treatment for gender dysphoria and is not a surgery meant to affect reproduction, just as a hysterectomy on a cancer patient is not intended to affect procreation. While impacts on reproduction may be an incidental effect of some transgender-affirming care, such treatment is *not* "sterilization."

14. The Denial-of-Care Rule invites further discrimination justified by religious or moral beliefs against the Center's patients and puts the health of LGBT patients at risk. The Rule encourages LGBT patients to attempt to hide their LGBT identities when seeking healthcare services, especially from religiously-affiliated healthcare organizations, in order to avoid discrimination. When patients are unwilling to disclose their sexual orientation and/or gender identity to healthcare providers out of fear of discrimination and being refused treatment, their mental and physical health is critically compromised.

15. The Denial-of-Care Rule also adversely impacts the Center by necessitating the diversion and reallocation of resources in order to provide referrals to patients, including for patients that the Center does not have the resources to treat because of increased demand for the Center's services as a result of the Rule. The Denial-of-Care Rule will cause an increased number of LGBT patients and patients living with HIV to seek the Center's assistance in finding LGBT-affirming healthcare providers. The Center will also have more difficulty finding LGBT-affirming healthcare providers, especially those with niche specialties, given that the Rule emboldens healthcare providers to refuse to treat LGBT patients.

16. The increase in referral requests requires the Center to allocate additional staff time to pre-screen service referrals to ensure that staff are sending patients to LGBT-affirming providers and not to providers who themselves or whose staff would cause additional harm to the Center's patients. As a result of the Denial-of-Care Rule, the Center may need to hire a case-manager to address the community's need for referrals to welcoming providers. The Center's staff and resources have already been spent engaging in advocacy, policy analysis, and services to address the ill-effects of the Denial-of-Care Rule. The Center will also have to divert resources away from other programming to conduct informational sessions about the Denial-of-Care Rule to answer patients' and staff members' questions about how the Rule will affect them and the services that the Center provides.

17. It will be increasingly difficult to determine whether job applicants will be unwilling to perform essential job functions, which is likely to undermine the Center's philosophy of fostering a diverse workforce. The Center's current recruiting process is developed to ascertain whether a job applicant will provide healthcare consistent with the Center's mission to establish a welcoming, nondiscriminatory environment for all patients and staff, without violating the law. Providing care in a non-discriminatory and inclusive manner, putting aside people's individual religious or moral

beliefs, is a core part of the Center' job criteria for new applicants. If the Center can no longer inquire about whether an applicant will decide which patients to treat on the basis of religious principles that are inconsistent with the Center's mission, hiring managers will be in a complex position of trying to ascertain whether those job candidates might cause harm to patients while at the same time considering risks and requirements under the Denial-of-Care Rule. The Center cannot alter those job criteria without thwarting its mission.

18. Furthermore, if the Center is required to get the consent of religious or moral objectors to a proposed accommodation for their religious beliefs, the Center's operations will be negatively affected, resulting in potential delays in treatment, prevention, and other supportive health services to patients. Under the broad and vague language of the Denial-of-Care Rule, the Center will constantly fear the realistic possibility that any of its staff – from janitorial to cafeteria or security personnel – could discriminate against the Center's patients on the basis of religious beliefs, causing extreme harm to the Center's patients and mission. The Center will have no recourse to reassure its patients that the Center is a safe and affirming place for them to seek healthcare, which could cause irreparable damage to the Center's reputation. Likewise, implementation of the notice provision in the Denial-of-Care Rule that implicitly puts the onus on patients to request an LGBT-affirming healthcare provider who will not have a religious-based objection to treating such patients would result in immediate negative responses from clients and erode patient trust, further thwarting the Center's mission.

19. In short, the Denial-of-Care Rule makes it difficult, if not impossible, for the Center to continue providing the same level of social, mental, and physical healthcare to its patients. The Center's mission includes addressing the need for equity in healthcare for all of the Center's patients and the LGBT community generally. This mission will be frustrated by the Denial-of-Care Rule as there will be a decline in overall LGBT-patient health and public health at large.

# Case 5:19-cv-02916-NC Document 36-8 Filed 06/11/19 Page 12 of 12 I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Dated: June 9, 2019 Respectfully submitted, /s/ Darrel Cummings Darrel Cummings - 11 -

1 2 3 4 5 6 7 8 9	RICHARD B. KATSKEE* AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE 1310 L Street NW, Suite 200 Washington, DC 20005 Tel: (202) 466-3234; Fax: (202) 466-3234 katskee@au.org GENEVIEVE SCOTT* CENTER FOR REPRODUCTIVE RIGHTS 199 Water Street, 22nd Floor New York, NY 10038 Tel: (917) 637-3605; Fax: (917) 637-3666 gscott@reprorights.org  JAMIE A. GLIKSBERG* LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. 105 West Adams, 26th Floor Chicago, IL 60603-6208	JAMES R. WILLIAMS (SBN 271253) GRETA S. HANSEN (SBN 251471) LAURA S. TRICE (SBN 284837) MARY E. HANNA-WEIR (SBN 320011) SUSAN P. GREENBERG (SBN 318055) H. LUKE EDWARDS (SBN 313756) OFFICE OF THE COUNTY COUNSEL, COUNTY OF SANTA CLARA 70 West Hedding Street, East Wing, 9th Fl. San José, CA 95110-1770 Tel: (408) 299-5900; Fax: (408) 292-7240 mary.hanna-weir@cco.sccgov.org  LEE H. RUBIN (SBN 141331) MAYER BROWN LLP Two Palo Alto Square, Suite 300 3000 El Camino Real Palo Alto, CA 94306-2112 Tel: (650) 331-2000; Fax: (650) 331-2060
11	Tel: (312) 663-4413; Fax: (312) 663-4307 jgliksberg@lambdalegal.org	lrubin@mayerbrown.com  Counsel for Plaintiffs
12		
13	UNITED STATES I NORTHERN DISTRIC	
14   15   16   17   18   19   20   21   22   23   24   25   26   27   28	COUNTY OF SANTA CLARA, TRUST WOMEN SEATTLE, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC, INC. d/b/a WHITMAN-WALKER HEALTH, BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS d/b/a GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, and RANDY PUMPHREY,  Plaintiffs,  vs.  U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES and ALEX M. AZAR, II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES,  Defendants.	Case No. 5:19-cv-2916  DECLARATION OF DR. RANDI C. ETTNER, PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
28	Defendants.	

I, Dr. Randi C. Ettner, declare as follows:

- 1. I have been retained by counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury-Sullivan LGBT Community Center, Center On Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association Of LGBTQ+ Psychiatrists, American Association of Physicians for Human Rights d/b/a Glma: Health Professionals Advancing LGBTQ Equality, Colleen Mcnicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey as an expert in connection with the above-captioned matter.
  - 2. I submit this expert declaration based on my personal knowledge.
- 3. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

### I. BACKGROUND AND QUALIFICATIONS

# **Qualifications and Basis for Opinion**

- 4. I am a licensed clinical and forensic psychologist with a specialization in the diagnosis, treatment, and management of gender dysphoric individuals. I received my doctorate in psychology (with honors) from Northwestern University. I am a Fellow and Diplomate in Clinical Evaluation of the American Board of Psychological Specialties, and a Fellow and Diplomate in Trauma/Post-Traumatic Stress Disorder.
- 5. I was the chief psychologist at the Chicago Gender Center from 2005 to 2016, when it moved to Weiss Memorial Hospital. Since that time, I have held the sole psychologist position at the Center for Gender Confirmation Surgery at Weiss Memorial Hospital. A true and accurate copy of my curriculum vitae is attached as Exhibit A to this declaration.
- 6. I have evaluated, diagnosed, and treated between 2,500 and 3,000 individuals with gender dysphoria and mental health issues related to gender variance from 1980 to present. I have

published four books related to the treatment of individuals with gender dysphoria, including the medical text entitled <u>Principles of Transgender Medicine and Surgery</u> (1st edition, co-editors Monstrey & Eyler; Rutledge 2007; and 2nd edition, coeditors Monstrey & Coleman; Routledge, June 2016). In addition, I have authored numerous articles in peer-reviewed journals regarding the provision of health care to the transgender population.

- 7. I have served as a member of the University of Chicago Gender Board, and am on the editorial boards of *The International Journal of Transgenderism and Transgender Health*. I am the secretary and a member of the Board of Directors of the World Professional Association of Transgender Health (WPATH), and an author of the WPATH *Standards of Care for the Health of Transsexual, Transgender and Gender Nonconforming People* (7th version), published in 2011. The WPATH promulgated *Standards of Care* ("*Standards of Care*") are the internationally recognized guidelines for the treatment of persons with gender dysphoria and serve to inform medical treatment in the United States and throughout the world.
- 8. I chair the WPATH Committee for Institutionalized Persons, and provide training to medical professionals on healthcare for transgender inmates. I have lectured throughout North America, Europe, and Asia on topics related to gender dysphoria and present grand rounds on gender dysphoria at university hospitals. I am the honoree of the externally-funded Randi and Fred Ettner Fellowship in Transgender Health at the University of Minnesota. I have been an invited guest at the National Institute of Health to participate in developing a strategic research plan to advance the health of sexual and gender minorities, and in November 2017 was invited to address the Director of the Office of Civil Rights of the United States Department of Health and Human Services regarding the medical treatment of gender dysphoria. I received a commendation from the United States Congress House of Representatives on February 5, 2019 recognizing my work for WPATH and GD in Illinois.

9. I have been retained as an expert regarding gender dysphoria and the treatment of gender dysphoria in multiple court cases in both state and federal courts as well as administrative proceedings. I have also been a consultant to policy makers regarding appropriate care for transgender inmates and for Centers for Medicare and Medicaid in the state of Illinois.

10. Attached as Exhibit B is a bibliography of relevant medical and scientific materials related to transgender people and gender dysphoria. I generally rely on these materials when I provide expert testimony, in addition to the documents specifically cited as supportive examples in particular sections of this declaration. I have also relied on my years of experience in this field, as set out in my curriculum vitae (Exhibit A), and on the materials listed therein. The materials I have relied on in preparing this declaration are the same type of materials that experts in my field of study regularly rely upon when forming opinions on the subject.

#### Compensation

11. I am being compensated for my work on this matter at a rate of \$375.00 per hour for preparation of declarations and expert reports. I will be compensated \$500.00 per hour for any predeposition and/or pre-trial preparation and any deposition testimony or trial testimony. I will receive a flat fee of \$2,500.00 for any travel time to attend deposition or trial, and will be reimbursed for reasonable out-of-pocket travel expenses incurred for the purpose of providing expert testimony in this matter. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

#### **Previous Testimony**

12. In the last four years, I have testified as an expert at trial or by deposition in the following cases: Soneeya v. Turco, No. 07-12325-DPW (D. Mass. 2019); Edmo v. Idaho Dep't of Correction, No. 1:17-CV-00151-BLW, 2018 WL 2745898 (D. Idaho 2018); Carillo v U.S. Dep't of Justice Exec. (Office of Immig. Rev. 2017); Broussard v. First Tower Loan, LLC, 135 F. Supp.

3d 540 (E.D. La. 2016); Faiella v. American Medical Response of Connecticut, Inc., No. HHD-CV15-6061263-S (Conn. Super. Ct.); Kothmann v. Rosario, 558 F. App'x 907 (11th Cir. 2014).

#### II. EXPERT OPINIONS

#### **Gender Identity and Gender Dysphoria**

- 13. A person's sex is comprised of a number of components including, *inter alia*: chromosomal composition (detectible through karyotyping); gonads and internal reproductive organs (detectible by ultrasound, and occasionally by a physical pelvic exam); external genitalia (which are visible at birth); sexual differentiations in brain development and structure (detectible by functional magnetic resonance imaging studies and autopsy); and gender identity.
- 14. Gender identity is a well-established concept in medicine. Gender identity refers to a person's inner sense of belonging to a particular sex, such as male or female. It is a deeply felt and core component of human identity. All human beings develop this elemental internal view: the conviction if belonging to a particular gender, such as male or female. Gender identity is innate, has biological underpinnings, and is firmly established early in life.
- 15. When there is divergence between anatomy and identity, one's gender identity is paramount and the primary determinant of an individual's sex designation. Developmentally, it is the overarching determinant of the self-system, influencing personality, a sense of mastery, relatedness, and emotional reactivity, across the life span. It is also the foremost predictor of satisfaction and quality of life. Efforts to change an individual's gender identity are harmful, futile, and unethical.
- 16. At birth, individuals are assigned a sex, typically male or female, based solely on the appearance of their external genitalia. For most people, that assignment turns out to be accurate, and their birth-assigned sex matches that person's actual sex. However, for transgender individuals, this is not the case.

- 17. For transgender individuals, the sense of one's self—one's gender identity—differs from the sex they were assigned at birth, giving rise to a sense of being "wrongly embodied."
- 18. The medical diagnosis for that feeling of incongruence and accompanying distress is gender dysphoria, a serious medical condition, formerly known as gender identity disorder ("GID"). Gender Dysphoria is a diagnosis codified in the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5"). The critical element of the Gender Dysphoria diagnosis is the presence of symptoms that meet the threshold for clinical impairment. This represents a change from GID, which focused on an individual's *identity* being disordered. This new diagnostic term, Gender Dysphoria, is also an acknowledgment that gender incongruence, in and of itself, does not constitute a mental disorder. As recently as June 16, 2018, the World Health Organization ("WHO") likewise announced it was reclassifying the gender incongruence diagnosis in the forthcoming International Classification of Diseases-11 ("ICD-11"). This is significant because it removes "gender identity disorder" from the chapter on mental and behavioral disorders, recognizing that gender incongruence is not a mental illness, and instead incorporates it within a new chapter dedicated to sexual health.
- 19. The condition is characterized by incongruence between one's experienced/expressed gender and assigned sex at birth, and clinically significant distress or impairment of functioning that results. Gender dysphoria is manifested by symptoms such as preoccupation with ridding oneself of the primary and/or secondary sex characteristics associated with one's birth- assigned sex. Untreated gender dysphoria can result in significant clinical distress, debilitating depression, and suicidality.
  - 20. The diagnostic criteria for gender dysphoria in adults are as follows:
    - a. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 month's duration, as manifested by at least two of the following:

- i. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics.
- ii. A strong desire to be rid of one's primary and/or secondary sex characteristics.
- iii. A strong desire for the primary and/or secondary sex characteristics of the other gender.
- iv. A strong desire to be of the other gender.
- v. A strong desire to be treated as the other gender.
- vi. A strong conviction that one has the typical feelings and reactions of the other gender.
- b. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.
- 21. Gender dysphoria is a highly treatable condition. Without treatment, however, individuals with gender dysphoria experience anxiety, depression, suicidality, and other attendant mental health issues. They are also frequently isolated because they carry a burden of shame and low self-esteem, attributable to the feeling of being inherently "defective." This leads to stigmatization, and over time, ravages healthy personality development and interpersonal relationships. As a result, without treatment many such individuals are unable to function effectively in daily life. Studies show a 41%-43% rate of suicide attempts among this population, far above the baseline for North America (Haas et al., 2014).
- 22. Gender dysphoric patients who are assigned a male sex at birth but identify as female and lack access to appropriate care are often so desperate for relief that they may resort to life-threatening attempts at auto-castration—removal of the testicles—in the hopes of eliminating the major source of testosterone that kindles the distress (Brown, 2010; Brown & McDuffie, 2009).
- 23. Gender dysphoria generally intensifies with age. As gender dysphoric individuals approach middle age, they experience an exacerbation of symptoms (Ettner, 2013; Ettner & Wiley, 2013).

//

//

#### **Treatment of Gender Dysphoria**

- 24. The standards of care for treating gender dysphoria are set forth in the WPATH Standards of Care, first published in 1979. The Standards of Care are the internationally recognized guidelines for the treatment of persons with gender dysphoria, and inform medical treatment throughout the world, and in this country. The American Medical Association, the Endocrine Society, the American Psychological Association the American Psychiatric Association, the World Health Organization, the American Academy of Family Physicians, the American Public Health Association, the National Association of Social Workers, the American College of Obstetrics and Gynecology and the American Society of Plastic Surgeons all endorse protocols in accordance with the WPATH standards. See, e.g., American Medical Association (2008) Resolution 122 (A-08); Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (2017); American Psychological Association Policy Statement on Transgender, Gender Identity & Gender Expression Non-discrimination (2008).
- 25. The Standards of Care identify the following evidence-based protocols for the treatment of individuals with gender dysphoria:
  - Changes in gender expression and role, consistent with one's gender identity (social role transition)
  - Psychotherapy for purposes such as addressing the negative impact of stigma, alleviating internalized transphobia, enhancing social and peer support, improving body image, promoting resiliency, etc.
  - Hormone therapy to feminize or masculinize the body
  - Surgery to alter primary and/or secondary sex characteristics (e.g., breasts, external genitalia, facial features, body contouring)
- 26. The ability to live in a manner consistent with one's gender identity is critical to a person's health and well-being and is a key aspect in the treatment of gender dysphoria. The process by which transgender people come to live in a manner consistent with their gender identity, rather than the sex they were assigned at birth, is known as transition. The steps that each

transgender person takes to transition are not identical. Whether any particular treatment is medically necessary or even appropriate depends on the medical needs of the individual.

- 27. Once a diagnosis is established, a treatment plan should be developed based on the individualized assessment of the medical needs of the patient. WPATH specifies that treatment plans and provision of care must be undertaken by qualified professionals, with established competencies in the treatment of gender dysphoria (Section VIII).
- 28. **Psychotherapy:** Psychotherapy can provide support and help with many issues that arise in tandem with gender dysphoria. However, psychotherapy alone is not a substitute for medical intervention when medical interventions are required, nor is it a precondition for medically indicated treatment. By analogy, counseling can be useful for patients with diabetes by providing psychoeducation about living with chronic illness and nutritional information, but counseling does not obviate the need for insulin.
- 29. **Social Role Transition:** The Standards of Care establish the therapeutic importance of changes in gender expression and presentation—the ability to feminize or masculinize one's appearance— as a critical component of treatment. Known as the "real life experience," it requires dressing, grooming, and otherwise conveying, via social signifiers, a public face and role consistent with one's gender identity. This is an appropriate and essential part of identity consolidation. Through this experience, the transgender individual can begin to address the shame some experience of growing up living as a "false self" and the grief of being born in the "wrong body." (Greenberg and Laurence, 1981; Ettner, 1999; Devor, 2004; Bockting, 2007.)
- 30. Hormone Therapy: For individuals with persistent, well-documented gender dysphoria, hormone therapy is an essential, medically indicated treatment to alleviate the distress of the condition. Cross sex hormone administration is a well-established and effective treatment modality for gender dysphoria. The American Medical Association, the Endocrine Society, the

American Psychiatric Association and the American Psychological Association all concur that hormone therapy, provided in accordance with the WPATH *Standards of Care*, is the medically necessary, evidence-based, best practice care for most patients with gender dysphoria.

- 31. The goals of hormone therapy are (1) to significantly reduce hormone production associated with the person's birth sex, causing the unwanted secondary sex characteristics to recede, and (2) to replace the natal, circulating sex hormones with either feminizing or masculinizing hormones, using the principles of hormone replacement treatment developed for hypogonadal patients (i.e. those born with insufficient sex steroid hormones). See Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (2017); Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline (2009).
- 32. The therapeutic effects of hormone therapy are twofold: (1) with endocrine treatment, the patient acquires congruent secondary sex characteristics, i.e., breast development, redistribution of body fat, cessation of male pattern baldness, and reduction of body hair; and (2) hormones act directly on the brain, via receptor sites, attenuating the dysphoria and attendant psychiatric symptoms, and promoting a sense of well-being.
- 33. For many patients, hormones alone will not provide sufficient breast development to approximate the female torso. For these patients, breast augmentation has a dramatic, irreplaceable, and permanent effect on reducing gender dysphoria, and thus unquestionable therapeutic results.
- 34. **Surgical Treatment:** For individuals with severe gender dysphoria, hormone therapy alone is insufficient. In these cases, dysphoria does not abate without surgical intervention. For transgender women, genital confirmation surgery has two therapeutic purposes. First, removal of the testicles eliminates the major source of testosterone in the body. Second, the patient attains

body congruence resulting from the normal appearing and functioning female uro-genital structures. Both outcomes are crucial in attenuating or eliminating gender dysphoria. Additionally, breast augmentation procedures play the critical role in treatment mentioned in the paragraph immediately above.

- demonstrated that gender confirmation surgery is a safe and effective treatment for severe gender dysphoria and, indeed, for many, it is the only effective treatment. The American Medical Association, the Endocrine Society, the American Psychological Association, and the American Psychiatric Association all endorse surgical therapy, in accordance with the WPATH Standards of Care, as medically necessary treatment for individuals with severe gender dysphoria. See American Medical Association (2008), Resolution 122 (A-08); Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline (2017) ("For many transgender adults, genital gender-affirming surgery may be the necessary step toward achieving their ultimate goal of living successfully in their desired gender role."); American Psychological Association Policy Statement on Transgender, Gender Identity and Gender Expression Nondiscrimination (2009) (recognizing "the efficacy, benefit and medical necessity of gender transition treatments" and referencing studies demonstrating the effectiveness of sex-reassignment surgeries).
- 36. Surgeries are considered "effective" from a medical perspective, if they "have a therapeutic effect" (Monstrey et al. 2007). More than three decades of research confirms that gender confirmation surgery is therapeutic and therefore an effective treatment for gender dysphoria. Indeed, for many patients with severe gender dysphoria, gender confirmation surgery is the only effective treatment.

- 37. In a 1998 meta-analysis, Pfafflin and Junge reviewed data from 80 studies, from 12 countries, spanning 30 years. They concluded that "reassignment procedures were effective in relieving gender dysphoria. There were few negative consequences and all aspects of the reassignment process contributed to overwhelmingly positive outcomes" (Pfafflin & Junge 1998).
- 38. Numerous subsequent studies confirm this conclusion. Researchers reporting on a large-scale prospective study of 325 individuals in the Netherlands concluded that after surgery there was "a virtual absence of gender dysphoria" in the cohort and "results substantiate previous conclusions that sex reassignment is effective" (Smith et al. 2005). Indeed, the authors of the study concluded that the surgery "appeared therapeutic and beneficial" across a wide spectrum of factors and "[t]he main symptom for which the patients had requested treatment, gender dysphoria, had decreased to such a degree that it had disappeared."
- As a general matter, patient satisfaction is a relevant measure of effective treatment. Achieving functional and normal physical appearance consistent with gender identity alleviates the suffering of gender dysphoria and enables the patient to function in everyday life. Studies have shown that by alleviating the suffering and dysfunction caused by severe gender dysphoria, gender confirmation surgery improves virtually every facet of a patient's life. This includes satisfaction with interpersonal relationships and improved social functioning (Rehman et al., 1999; Johansson et al., 2010; Hepp et al.; 2002; Ainsworth & Spiegel, 2010; Smith et al., 2005); improvement in self-image and satisfaction with body and physical appearance (Lawrence, 2003; Smith et al., 2005; Weyers et al., 2009); and greater acceptance and integration into the family (Lobato et al., 2006).
- 40. Studies have also shown that surgery improves patients' abilities to initiate and maintain intimate relationships (Lobato et al., 2006; Lawrence, 2005; Lawrence, 2006; Imbimbo et al., 2009; Klein & Gorzalka, 2009; Jarolim et al., 2009; Smith et al., 2005; Rehman et al., 1999; DeCuypere et al., 2005).

- 41. Given the decades of extensive experience and research supporting the effectiveness of gender confirmation surgery, it is clear that reconstructive surgery is a medically necessary, not experimental, treatment for gender dysphoria. Therefore, decades of peer-reviewed research and a medical consensus support the inclusion of gender confirmation surgery as a medically necessary treatment in the WPATH *Standards of Care*.
- 42. In 2016 WPATH issued a "Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A." ("Position Statement"), affirming a statement originally issued in 2008. As the Position Statement explains, "These medical procedures and treatment protocols are not experimental: Decades of both clinical experience and medical research show they are essential to achieving well-being for the transsexual patient."
- 43. Similarly, Resolution 122 (A-08) of the American Medical Association states: "Health experts in GID, including WPATH, have rejected the myth that these treatments are 'cosmetic' or 'experimental' and have recognized that these treatments can provide safe and effective treatment for a serious health condition."
- 44. On May 30, 2014, the Appellate Division of the Departmental Appeals Board of the United States Department of Health and Human Services issued decision number 2576, in which the Board determined that Medicare's policy barring coverage for transition-related surgeries was not valid under the "reasonableness standard." The Board found that the ban "was based principally on" a report from 1981 that has been rendered obsolete by numerous "medical studies published in the more than 32 years since issuance of the 1981 report." The Board specifically concluded that transition-related surgeries are "safe and effective and not experimental." As a result, Medicare's exclusion was struck down and Medicare was directed to consider surgeries on a case-by-case basis.

- 45. The overwhelming scientific evidence indicates that transition-related care, including gender confirmation surgery, is medically necessary for the treatment of gender dysphoria in some patients.
- 46. Equating treatment gender confirmation surgery that has been prescribed to treat gender dysphoria with sterilization is medically inaccurate. Procedures undertaken for the purpose of sterilization are distinct from medical procedures undertaken for other purposes that incidentally affect reproductive function.
- 47. For some transgender people who desire children, reproduction may be possible even when such individuals have obtained transition-related medical care. For example, prior to the initiation of cross sex hormones, the preservation of gametes allows for future possible conception. If hormonal treatment for gender dysphoria has been initiated, it can be discontinued, and harvesting to retrieve gametes or stimulation of testicles or ovaries can be utilized for conception. In addition, for transgender men who retain a uterus, the discontinuation of masculinizing hormones may allow for pregnancy and childbirth.

## The Harmful Effects of Denial-of-Care to Transgender People

48. The overarching goal of treatment is to eliminate the distress of gender dysphoria by aligning an individual patient's body and presentation with their internal sense of self, thereby consolidating identity. Developing and integrating a positive sense of self-identity formation is a fundamental undertaking for all human beings. Denial of medically indicated care to transgender people based on moral or religious objections signals that such people are "inferior" or "unworthy," and triggers shame. The "Denial of Care Rule" provides a license to discriminate and challenges the legitimacy of identity. In so doing, the Rule erodes resilience and poses lifelong health risks to transgender and gender nonconforming individuals, including depression, posttraumatic stress disorder, cardiovascular and other disease, premature death and suicide.

- 49. A wealth of research establishes that transgender people suffer from discrimination, stigma and shame. The "minority stress model" explains that the negative impact of the stress attached to being stigmatized is socially based. The stress process can be both external, *i.e.*, actual experiences of rejection and discrimination (enacted stigma), and as a result of such experiences, internal, *i.e.*, perceived rejection and the expectation of being rejected or discriminated against (felt stigma). A 2015 study of 28,000 transgender and gender nonconforming individuals found that 30% reported being fired, discriminated or otherwise experiencing mistreatment in the workplace. Similarly, 31% of respondents had been mistreated in a public place, including 14% who were denied service, 24% who were verbally harassed and 2% who were physically attacked.
- 50. This discrimination, often in the form of violence, abuse or harassment, is related to negative health outcomes. A 2012 study of transgender adults found fear of discrimination increased the risk of developing hypertension by 100%, owing to the intersectionality of shame and cardiovascular reactivity. Indeed, a 2012 study of discrimination and implications for health concluded: "living in states with discriminatory policies . . . was associated with a statistically significant increase in the number of psychiatric disorder diagnoses." Another study found transgender adults' access to college bathrooms and housing was related to suicidality.
- 51. Until recently, it was not fully understood that these experiences of shame and discrimination could have serious and enduring consequences. But it is now known that marginalization, stigmatization and victimization are some of the most powerful predictors of current and future mental health problems, including the development of psychiatric disorders. The social problems that young transgender people face actually create the blueprint for future mental health, life satisfaction, and even physical health. A recent study of 245 gender-nonconforming adults found that stress and victimization during childhood and adolescence was associated with a greater risk for post-traumatic stress disorder, depression, life dissatisfaction, anxiety, and

suicidality in adulthood. A 2011 Institute of Medicine (IOM) report concurs: "the marginalization of transgender people from society is having a devastating effect on their physical and mental health." And the American Journal of Public Health recently reported that more than half of transgender women "struggle with depression from the stigma, shame and isolation caused by how others treat them."

- 52. Conversely, Bauer et al. found a 62% reduction in risk of suicide ideation with the completion of medical transition. That corresponds to a potential prevention of 240 suicide attempts per 1,000 per year.
- 53. While there is a growing body of documentation that structural forms of stigma (policies) harm the health of transgender people, a 2010 study was the first to show that structural stigma is associated with *all-cause mortality* (i.e. deaths from any cause). In other words, stigma—a chronic source of psychological stress--disrupts physiological pathways, increasing disease vulnerability, and leading to premature death.
- 54. Adding to the corpus of research in this area is a relatively new approach to the investigation of the relationship between discrimination and health. Neuroscientists have discovered that, in addition to causing serious emotional difficulties and physical harms, discrimination, harassment and verbal abuse permanently alter the architecture of the brain. Deviations in the myelin sheathing of the corpus callosum and damage to the hippocampus cause cognitive difficulties in individuals who have been routinely subjected to humiliation and ostracism.
- 55. Transgender individuals currently face significant discrimination in health care settings and barriers to care. Forty percent (40%) fear accessing care, and forego routine screening and preventative care. A 2017 report by the Center for American Progress of 7,500 transgender adults found 29 % were refused treatment based on their gender identity and 21 % were verbally

1 abused when seeking healthcare. The report also found that transgender individuals often had to 2 travel to other states to find medical providers. A 2018 survey of 6,450 participants found 24% 3 were denied treatment in doctor's offices or hospitals, 13% in emergency rooms, 11% in mental 4 health clinics and 5% for ambulance or emergency medical services. As a result, transgender 5 individuals have poorer health, greater stress, and higher rates of obesity, even when compared to 6 lesbian and gay populations. Indeed, 23% of respondents to a 2015 study did not see a doctor when 7 they needed to because of fear of being mistreated as a transgender person. These findings led to 8 9 the Association of American Medical Colleges to convene an advisory committee to develop 10 curricula based on competencies for medical education. 11 56. "The Denial of Care Rule" further endangers the health and well being of vulnerable 12 individuals by permitting providers to refuse healthcare on the basis of religious or moral objections 13 to transgender individuals' identities. The Rule seeks to create a license to discriminate, posing a 14 serious risk to transgender people. The harms that will befall transgender people are predictable 15 16 and dire: the exacerbation of symptoms of gender dysphoria, grave damage to mental and physical 17 health, and the undermining of clearly established, evidence based treatment protocols. 18 // 19 // 20 // 21 // 22 // 23 24 // 25 // 26 // 27

//

28

## Case 5:19-cv-02916-NC Document 36-9 Filed 06/11/19 Page 18 of 38

1	I declare under penalty of perjury under the laws of the United States of America that the
2	foregoing is true and correct.
3	Dated this 5th day of June, 2019.
4	
5	Respectfully submitted,
6	
7	/s/ Dr. Randi C. Ettner Dr. Randi C. Ettner
8	
9	
10	
11	
12 13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
26	
27	
28	
	- 17 -

# **EXHIBIT A**

## RANDI ETTNER, PHD 1214 Lake Street Evanston, Illinois 60201 847-328-3433

### **POSITIONS HELD**

Clinical Psychologist

Forensic Psychologist

Fellow and Diplomate in Clinical Evaluation, American Board of

**Psychological Specialties** 

Fellow and Diplomate in Trauma/PTSD

President, New Health Foundation Worldwide

Secretary, World Professional Association of Transgender Healthcare

(WPATH)

Chair, Committee for Institutionalized Persons, WPATH

Global Education Initiative Committee

University of Minnesota Medical Foundation: Leadership Council

Psychologist, Center for Gender Confirmation Surgery, Weiss Memorial

Hospital

Adjunct Faculty, Prescott College

Editorial Board, International Journal of Transgenderism

Editorial Board, Transgender Health

Television and radio guest (more than 100 national and international

appearances)

Internationally syndicated columnist

Private practitioner

Medical staff Weiss Memorial Hospital, Chicago IL

### **EDUCATION**

PhD, 1979	Northwestern University (with honors) Evanston, Illinois
MA, 1976	Roosevelt University (with honors) Chicago, Illinois
BA, 1969-73	Indiana University Bloomington, Indiana Cum Laude Major: Clinical Psychology; Minor: Sociology
1972	Moray College of Education Edinburgh, Scotland International Education Program
1970	Harvard University Cambridge, Massachusetts Social Relations Undergraduate Summer Study Program in Group Dynamics and Processes

## **CLINICAL AND PROFESSIONAL EXPERIENCE**

2016-present	Psychologist: Weiss Memorial Hospital Center for Gender Confirmation Surgery Consultant: Walgreens; Tawani Enterprises Private practitioner
2011	Instructor, Prescott College: Gender-A multidimensional approach
2000	Instructor, Illinois Professional School of Psychology
1995-present	Supervision of clinicians in counseling gender non conforming clients
1993	Post-doctoral continuing education with Dr. James Butcher in MMPI-2 Interpretation, University of Minnesota
1992	Continuing advanced tutorial with Dr. Leah Schaefer in psychotherapy
1983-1984	Staff psychologist, Women's Health Center, St. Francis Hospital, Evanston, Illinois
1981-1984	Instructor, Roosevelt University, Department of Psychology: Psychology of Women, Tests and Measurements, Clinical Psychology, Personal Growth, Personality Theories, Abnormal Psychology
1976-1978	Research Associate, Cook County Hospital, Chicago, Illinois, Department of Psychiatry
1975-1977	Clinical Internship, Cook County Hospital, Chicago, Illinois, Department of Psychiatry
1971	Research Associate, Department of Psychology, Indiana University
1970-1972	Teaching Assistant in Experimental and Introductory Psychology Department of Psychology, Indiana University
1969-1971	Experimental Psychology Laboratory Assistant, Department of Psychology, Indiana University

## **LECTURES AND HOSPITAL GRAND ROUNDS PRESENTATIONS**

Mental health issues in transgender health care, American Medical Student Association, webinar presentation, 2019

Sticks and stones: Childhood bullying experiences in lesbian women and transmen, Buenos Aires, 2018

Gender identity and the Standards of Care, American College of Surgeons, Boston, MA, 2018 The mental health professional in the multi-disciplinary team, pre-operative evaluation and assessment for gender confirmation surgery, American Society of Plastic Surgeons, Chicago, IL, 2018; Buenos Aires, 2018

Navigating Transference and Countertransference Issues, WPATH global education initiative, Portland, OR; 2018

Psychological aspects of gender confirmation surgery International Continence Society, Philadelphia, PA 2018

The role of the mental health professional in gender confirmation surgeries, Mt. Sinai Hospital, New York City, NY, 2018

Mental health evaluation for gender confirmation surgery, Gender Confirmation Surgical Team, Weiss Memorial Hospital, Chicago, IL 2018

*Transitioning; Bathrooms are only the beginning, American College of Legal Medicine, Charleston, SC, 2018* 

*Gender Dysphoria: A medical perspective,* Department of Health and Human Services, Office for Civil Rights, Washington, D.C, 2017

*Multi-disciplinary health care for transgender patients*, James A. Lovell Federal Health Care Center, North Chicago, IL, 2017

Psychological and Social Issues in the Aging Transgender Person, Weiss Memorial Hospital, Chicago, IL, 2017.

Psychiatric and Legal Issues for Transgender Inmates, USPATH, Los Angeles, CA, 2017

Transgender 101 for Surgeons, American Society of Plastic Surgeons, Chicago, IL, 2017.

*Healthcare for transgender inmates in the US*, Erasmus Medical Center, Rotterdam, Netherlands, 2016.

Tomboys Revisited: Replication and Implication; Models of Care; Orange Isn't the New Black Yet- WPATH symposium, Amsterdam, Netherlands, 2016.

Foundations in mental health; role of the mental health professional in legal and policy issues, healthcare for transgender inmates; children of transgender parents; transfeminine genital surgery assessment: WPATH global education initiative, Chicago, IL, 2015; Atlanta, GA, 2016; Ft. Lauderdale, FL, 2016; Washington, D.C., 2016, Los Angeles, CA, 2017,

Minneapolis, MN, 2017, Chicago, IL, 2017; Columbus, Ohio, 2017; Portland, OR, 2018; Cincinnati, OH, 2018, Buenos Aires, 2018

Pre-operative evaluation in gender-affirming surgery-American Society of Plastic Surgeons, Boston, MA, 2015

Gender affirming psychotherapy; Assessment and referrals for surgery-Standards of Care-Fenway Health Clinic, Boston, 2015 Gender reassignment surgery- Midwestern Association of Plastic Surgeons, 2015

Adult development and quality of life in transgender healthcare- Eunice Kennedy Shriver National Institute of Child Health and Human Development, 2015

Healthcare for transgender inmates- American Academy of Psychiatry and the Law, 2014

Supporting transgender students: best school practices for success- American Civil Liberties Union of Illinois Safe School Alliance, 2014

Addressing the needs of transgender students on campus- Prescott College, 2014

The role of the behavioral psychologist in transgender healthcare – Gay and Lesbian Medical Association, 2013

Understanding transgender- Nielsen Corporation, Chicago, Illinois, 2013

Role of the forensic psychologist in transgender care; Care of the aging transgender patient-University of California San Francisco, Center for Excellence, 2013

Evidence-based care of transgender patients- North Shore University Health Systems, University of Chicago, Illinois, 2011; Roosevelt-St. Vincent Hospital, New York; Columbia Presbyterian Hospital, Columbia University, New York, 2011

*Children of Transsexuals*-International Association of Sex Researchers, Ottawa, Canada, 2005; Chicago School of Professional Psychology, 2005

*Gender and the Law-* DePaul University College of Law, Chicago, Illinois, 2003; American Bar Association annual meeting, New York, 2000

Gender Identity, Gender Dysphoria and Clinical Issues –WPATH Symposium, Bangkok, Thailand, 2014; Argosy College, Chicago, Illinois, 2010; Cultural Impact Conference, Chicago, Illinois, 2005; Weiss Hospital, Department of Surgery, Chicago, Illinois, 2005; Resurrection Hospital Ethics Committee, Evanston, Illinois, 2005; Wisconsin Public Schools, Sheboygan, Wisconsin, 2004, 2006, 2009; Rush North Shore Hospital, Skokie, Illinois, 2004; Nine Circles Community Health Centre, University of Winnipeg, Winnipeg, Canada, 2003; James H. Quillen VA Medical Center, East Tennessee State University, Johnson City, Tennessee, 2002; Sixth European Federation of Sexology, Cyprus, 2002; Fifteenth World

Congress of Sexology, Paris, France, 2001; Illinois School of Professional Psychology, Chicago, Illinois 2001; Lesbian Community Cancer Project, Chicago, Illinois 2000; Emory University Student Residence Hall, Atlanta, Georgia, 1999; Parents, Families and Friends of Lesbians and Gays National Convention, Chicago, Illinois, 1998; In the Family Psychotherapy Network National Convention, San Francisco, California, 1998; Evanston City Council, Evanston, Illinois 1997; Howard Brown Community Center, Chicago, Illinois, 1995; YWCA Women's Shelter, Evanston, Illinois, 1995; Center for Addictive Problems, Chicago, 1994

Psychosocial Assessment of Risk and Intervention Strategies in Prenatal Patients- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984; Purdue University School of Nursing, West Layette, Indiana, 1980

Psychonueroimmunology and Cancer Treatment- St. Francis Hospital, Evanston, Illinois, 1984

Psychosexual Factors in Women's Health- St. Francis Hospital, Center for Women's Health, Evanston, Illinois, 1984

Sexual Dysfunction in Medical Practice- St. Francis Hospital, Dept. of OB/GYN, Evanston, Illinois, 1980

*Sleep Apnea* - St. Francis Hospital, Evanston, Illinois, 1996; Lincolnwood Public Library, Lincolnwood, Illinois, 1996

The Role of Denial in Dialysis Patients - Cook County Hospital, Department of Psychiatry, Chicago, Illinois, 1977

#### **PUBLICATIONS**

Ettner, R., White, T., Ettner, F., Friese, T., Schechter, L. (2018) Tomboys revisited: A retrospective comparison of childhood behaviors in lesbians and transmen. *Journal of Child and Adolescent Psychiatry*.

Narayan, S., Danker, S Esmonde, N., Guerriero, J., Carter, A., Dugi III, D., Ettner, R., Radix A., Bluebond-Langner, R., Schechter, L., Berli, J. (2018) A survey study of surgeons' experience with regret and reversal of gender-confirmation surgeries as a basis for a multidisciplinary approach to a rare but significant clinical occurrence, submitted.

Ettner, R. Mental health evaluation. <u>Clinics in Plastic Surgery</u>. (2018) Elsevier, 45(3): 307-311.

Ettner, R. Etiology of gender dysphoria in Schechter (Ed.) <u>Gender Confirmation Surgery:</u> <u>Principles and Techniques for an Emerging Field.</u> Elsevier, 2017.

- Ettner, R. Pre-operative evaluation in Schechter (Ed.) <u>Surgical Management of the Transgender Patient</u>. Elsevier, 2017.
- Berli, J., Kudnson, G., Fraser, L., Tangpricha, V., Ettner, R., et al. Gender Confirmation Surgery: what surgeons need to know when providing care for transgender individuals. *JAMA Surgery*; 2017.
- Ettner, R., Ettner, F. & White, T. Choosing a surgeon: an exploratory study of factors influencing the selection of a gender affirmation surgeon. *Transgender Health*, 1(1), 2016.
- Ettner, R. & Guillamon, A. Theories of the etiology of transgender identity. In <u>Principles of Transgender Medicine and Surgery</u>. Ettner, Monstrey & Coleman (Eds.), 2nd edition; Routledge, June, 2016.
- Ettner, R., Monstrey, S, & Coleman, E. (Eds.) <u>Principles of Transgender Medicine and Surgery</u>, 2nd edition; Routledge, June, 2016.
- Bockting, W, Coleman, E., Deutsch, M., Guillamon, A., Meyer, I., Meyer, W., Reisner, S., Sevelius, J. & Ettner, R. Adult development and quality of life of transgender and gender nonconforming people. *Current Opinion in Endocrinology and Diabetes*, 2016.
- Ettner, R. Children with transgender parents in <u>Sage Encyclopedia of Psychology and Gender</u>. Nadal (Ed.) Sage Publications, 2017
- Ettner, R. Surgical treatments for the transgender population in <u>Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care. Ehrenfeld & Eckstrand, (Eds.) Springer: MA, 2016.</u>
- Ettner, R. Etiopathogenetic hypothesis on transsexualism in <u>Management of Gender Identity</u> <u>Dysphoria: A Multidisciplinary Approach to Transsexualism.</u> Trombetta, Liguori, Bertolotto, (Eds.) Springer: Italy, 2015.
- Ettner, R. Care of the elderly transgender patient. *Current Opinion in Endocrinology and Diabetes*, 2013, Vol. 20(6), 580-584.
- Ettner, R., and Wylie, K. Psychological and social adjustment in older transsexual people. *Maturitas*, March, 2013, Vol. 74, (3), 226-229.
- Ettner, R., Ettner, F. and White, T. Secrecy and the pathophysiology of hypertension. *International Journal of Family Medicine* 2012, Vol. 2012.
- Ettner, R. Psychotherapy in <u>Voice and Communication Therapy for the Transgender/Transsexual Client: A Comprehensive Clinical Guide</u>. Adler, Hirsch, Mordaunt, (Eds.) Plural Press, 2012.

- Coleman, E., Bockting, W., Botzer, M., Cohen-Kettenis, P., DeCuypere, G., Feldman, J., Fraser, L., Green, J., Knudson, G., Meyer, W., Monstrey, S., Adler, R., Brown, G., Devor, A., Ehrbar, R., Ettner, R., et.al. Standards of Care for the health of transsexual, transgender, and gender-nonconforming people. World Professional Association for Transgender Health (WPATH). 2012.
- Ettner, R., White, T., and Brown, G. Family and systems aggression towards therapists. *International Journal of Transgenderism*, Vol. 12, 2010.
- Ettner, R. The etiology of transsexualism in <u>Principles of Transgenger Medicine and Surgery</u>, Ettner, R., Monstrey, S., and Eyler, E. (Eds.). Routledge Press, 2007.
- Ettner, R., Monstrey, S., and Eyler, E. (Eds.) <u>Principles of Transgender Medicine and Surgery</u>. Routledge Press, 2007.
- Monstrey, S. De Cuypere, G. and Ettner, R. Surgery: General principles in <u>Principles of Transgender Medicine and Surgery</u>, Ettner, R., Monstrey, S., and Eyler, E. (Eds.) Routledge Press, 2007.
- Schechter, L., Boffa, J., Ettner, R., and Ettner, F. Revision vaginoplasty with sigmoid interposition: A reliable solution for a difficult problem. The World Professional Association for Transgender Health (WPATH), 2007, *XX Biennial Symposium*, 31-32.
- Ettner, R. Transsexual Couples: A qualitative evaluation of atypical partner preferences. *International Journal of Transgenderism*, Vol. 10, 2007.
- White, T. and Ettner, R. Adaptation and adjustment in children of transsexual parents. *European Journal of Child and Adolescent Psychiatry*, 2007: 16(4)215-221.
- Ettner, R. Sexual and gender identity disorders in <u>Diseases and Disorders</u>, Vol. 3, Brown Reference, London, 2006.
- Ettner, R., White, T., Brown, G., and Shah, B. Client aggression towards therapists: Is it more or less likely with transgendered clients? *International Journal of Transgenderism*, Vol. 9(2), 2006.
- Ettner, R. and White, T. in <u>Transgender Subjectives: A Clinician's Guide</u> Haworth Medical Press, Leli (Ed.) 2004.
- White, T. and Ettner, R. Disclosure, risks, and protective factors for children whose parents are undergoing a gender transition. *Journal of Gay and Lesbian Psychotherapy*, Vol. 8, 2004.
- Witten, T., Benestad, L., Berger, L., Ekins, R., Ettner, R., Harima, K. Transgender and Transsexuality. <u>Encyclopeida of Sex and Gender</u>. Springer, Ember, & Ember (Eds.) Stonewall, Scotland, 2004.

Ettner, R. Book reviews. Archives of Sexual Behavior, April, 2002.

Ettner, R. Gender Loving Care: A Guide to Counseling Gender Variant Clients. WW Norton, 2000.

"Social and Psychological Issues of Aging in Transsexuals," proceedings, Harry Benjamin International Gender Dysphoria Association, Bologna, Italy, 2005.

"The Role of Psychological Tests in Forensic Settings," Chicago Daily Law Bulletin, 1997.

<u>Confessions of a Gender Defender: A Psychologist's Reflections on Life amongst the Transgender.</u> Chicago Spectrum Press. 1996.

"Post-traumatic Stress Disorder," Chicago Daily Law Bulletin, 1995.

"Compensation for Mental Injury," Chicago Daily Law Bulletin, 1994.

"Workshop Model for the Inclusion and Treatment of the Families of Transsexuals," Proceedings of the Harry Benjamin International Gender Dysphoria Symposium; Bavaria, Germany, 1995.

"Transsexualism- The Phenotypic Variable," Proceedings of the XV Harry Benjamin International Gender Dysphoria Association Symposium; Vancouver, Canada, 1997.

"The Work of Worrying: Emotional Preparation for Labor," <u>Pregnancy as Healing. A Holistic Philosophy for Prenatal Care</u>, Peterson, G. and Mehl, L. Vol. II. Chapter 13, Mindbody Press, 1985.

## **PROFESSIONAL AFFILIATIONS**

University of Minnesota Medical School–Leadership Council
American College of Forensic Psychologists
World Professional Association for Transgender Health
World Health Organization (WHO) Global Access Practice Network
TransNet national network for transgender research
American Psychological Association
American College of Forensic Examiners
Society for the Scientific Study of Sexuality
Screenwriters and Actors Guild
Phi Beta Kappa

#### **AWARDS AND HONORS**

Letter of commendation from United States Congress for contributions to public health in Illinois, 2019

WPATH Distinguished Education and Advocacy Award, 2018

The Randi and Fred Ettner Transgender Health Fellowship-Program in Human Sexuality,
University of Minnesota, 2016
Phi Beta Kappa, 1972
Indiana University Women's Honor Society, 1970-1972
Indiana University Honors Program, 1970-1972
Merit Scholarship Recipient, 1970-1972
Indiana University Department of Psychology Outstanding Undergraduate Award
Recipient, 1970-1972
Representative, Student Governing Commission, Indiana University, 1970

## **LICENSE**

Clinical Psychologist, State of Illinois, 1980

# **EXHIBIT B**

#### BIBLIOGRAPHY

Ainsworth, T. & Spiegel, J. (2010). Quality of life of individuals with and without facial feminization surgery or gender reassignment surgery. *Quality of Life Research* 19(7): 1019-1024.

Amend, B., Seibold, J., Toomey, P., Stenzl, A., & Sievert, K. (2013). Surgical reconstruction for male-to-female sex reassignment. *European Urology* 64(1): 141-149.

American Medical Association (2008). Resolution 122 (A-08).

American Psychiatric Association (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

American Psychological Association (2012). Position Statement on Discrimination Against Transgender and Gender Variant Individuals.

American Psychological Association (2008). Transgender, gender identity, & gender expression non-discrimination.

Anton, B. (2009). Proceedings of the American Psychological Association for the legislative year 2008.

Bauer, G., Scheim, A., Pyne, J., et al (2015). Intervenable factors associated with suicide risk in transgender persons: a respondent driven sampling study in Ontario, Canada. *BMC Public Health* 15:525.

Benjamin, H. (1966). The Transsexual Phenomenon. New York: Julian Press.

Bentz, E.K., Hefler, L.A., Kaufman, U. et al (2008). A polymorphism of the CYP17 gene related to sex steroid metabolism is associated with female-to-male but not male-to-female transsexualism. *Fertility and Sterility* 90(1): 56-59.

Bockting, W. (2013). Transgender identity development. In Tolman & Diamond (eds.) <u>American Psychological Association's Handbook of Sexuality and Psychology</u>. Washington, D.C.: American Psychological Association.

Bockting, W., Coleman, E., Deutsch, M., Guillamon, A., Meyer, I., Meyer, W., Reisner, S., Sevelius, J. & Ettner, R. (2016). Adult development and quality of life of transgender and gender nonconforming people. *Current Opinion in Endocrinology and Diabetes* 23(2): 188-197.

Bockting, W. (2014). The impact of stigma on transgender identity development and mental health. In Kreukels, Steensma, and De Vries (eds). <u>Gender dysphoria and disorders of sex development: Progress in care and knowledge.</u> New York: Springer.

Bockting, W. & Coleman, E. (2007). Developmental stages of the transgender coming out process: Toward an integrated identity. Ettner, Monstrey & Eyler (eds.) <u>Principles of Transgender Medicine and Surgery</u>. New York: Haworth Press.

Bradford, J., Reisner, S., Honnold, J., Xavier, J. (2013). Experiences of transgender-related discrimination and implications for health: Results from the Virginia transgender health initiative study. *American Journal of Public Health* 103 (10).

Brown, G. (2010). Auto-castration and auto-penectomy as surgical self-treatment in incarcerated persons with Gender Identity disorder. *International Journal of Transgenderism* 12: 31-39.

Brown, G., & McDuffie, E. (2009). Health care policies addressing transgender inmates in prison systems in the United States. Journal of Correctional Health Care, 15, 280–291.

Budge, S., Adelson, J. & Howard, K. (2013). Anxiety and depression in transgender individuals: The role of transition status, loss, social support, and coping. *Journal of Consulting and Clinical Psychology* 81(3): 545.

Chung, W., De Vries, G., Swaab, D. (2002). Sexual differentiation of the bed nucleus of the stria terminalis in humans may extend into adulthood. *Journal of Neuroscience* 22(3): 1027-1033.

Cohen-Kettenis, P. & Gooren, L. (1992). The influence of hormone treatment on psychological functioning of transsexuals. In <u>Gender Dysphoria: Interdisciplinary Approaches in Clinical Management.</u> Bocting & Coleman (eds). Haworth Press.

Colizzi, M. et al. (2014). Transsexual patients' psychiatric comorbidity and positive effect of cross-sex hormonal treatment on mental health: Results from a longitudinal study. *Psychoneuroendocrinology* 39: 65-73.

Colton Meier, S., Fitzgerald, K., Pardo, S. & Babcock, J. (2011). The effects of hormonal gender affirmation treatment on mental health in female-to-male transsexuals. *Journal of Gay & Lesbian Mental Health* 15(3): 281-299.

Crocker, J., Major, B. & Steele, C. (1998). Social Stigma in Fiske & Gilbert (eds.) Handbook of Social Psychology, Vol 11.

DeCuypere, G, T'Sjoen, G. et al. (2005). Sexual and physical health after sex reassignment surgery. *Archives of Sexual Behavior* 34(6): 679-690.

Devor, A. (2004). Witnessing and mirroring: A fourteen stage model of transsexual identity formation. *Journal of Gay and Lesbian Psychotherapy* 8(1/2): 41-67.

Dhejne, C., Oberg, K., Arver, S., & Landen, M. (2013). Increasing incidence of sex reassignment applications but few regrets: A complete analysis of all applications during 50 years. *Journal of Sexual Medicine* 11: 8-9.

Diamond, M. (2013). Transsexuality among twins: identity concordance, transition, rearing, and orientation. *International Journal of Transgenderism* 14: 24-28.

Diamond, L., Pardo, S., Butterworth, M. (2011). Transgender experience and identity. In Schwartz et al (eds) <u>Handbook of Identity Theory and Research</u>: Springer.

Eldh, J., Berg, A., Gustafsson, M. (1997). Long term follow up after sex reassignment surgery, *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery* 31: 39-45.

Ettner, R. (1999). Gender loving care: A guide to counseling gender-variant clients. New York, NY, US: W W Norton & Co.

Ettner, R., Ettner, F. & White, T. (2012). Secrecy and the pathophysiology of hypertension. *International Journal of Family Medicine*: 2012.

Ettner, R. (2013). Care of the elderly transgender patient. *Current Opinion in Endocrinology and Diabetes, Vol.* 20(6), 580-584.

Ettner, R., and Wylie, K. (2013). Psychological and social adjustment in older transsexual people. *Maturitas* 74, (3), 226-229.

Ettner, R. (2015). Etiopathogenetic hypothesis on transsexualism. In Trombetta, Luguori & Bertolotto (eds) <u>Management of Gender Identity Dysphoria: A Multidimensional Approach to Transsexualism</u>. Italy: Springer.

Ettner, R., Guillamon, A. (2016). Theories of the etiology of transgenderism. In Principles of Transgender Medicine and Surgery. Ettner, Monstrey & Coleman (eds). New York: Routledge.

Fernandez, R., Esteva, I., Gomez-Gil, E., Rumbo, T. et al (2014). The (CA) in polymorphism of ERb gene is associated with FtM transsexualism. *Journal of Sexual Medicine* 11:720-728.

Frost, D., Lehavot, K. Meyer, I. (in press). Minority stress and physical health among sexual minority individuals. *Journal of Behavioral Medicine*. DOI: 10.1007/s10865-013-9523-8].

Galis, F., Ten Broek, C., Van Dongen, S., et al. (2010). Sexual dimorphism in the prenatal digit ratio (2D:4D). *Archives of Sexual Behavior* 39(1):57-62.

Garcia-Falgueras, A. & Swaab, D. A sex difference in the hypothalamic uncinate nucleus: relationship to gender identity. *Brain* 131: 3132-3146.

Gijs, L., & Brewayes, A. (2007). Surgical treatment of gender dysphoria in adults and adolescents: Recent developments, effectiveness, and challenges. *Annual Review of Sex Research* 18, 178-224.

Goffman, E. (1969). <u>The Presentation of Self in Everyday Life</u>. London: Allen Lane.

Gomez-Gil, E., Esteva, I., Almaraz, M,C. et al (2010). Familiarity of gender identity disorder in non-twin siblings. *Archives of Sexual Behavior* 39(2): 265-269.

Gomez-Gil, E., Zubiaurre-Elorza, L., Esteva, I., Guillamon, A. et al (2012). Hormone-treated transsexuals report less social distress, anxiety and depression. *Psychoneuroendocrinology* 37(5): 662-670.

Gorin-Lazard et al., (2011). Is hormonal therapy associated with better quality of life in transsexuals? A cross-sectional study. *Journal of Sexual Medicine* 9: 531-541.

Green, R. (2000). Family co-occurrence of "gender dysphoria": ten siblings or parent-child pairs. *Archives of Sexual Behavior* 29(5): 499-507.

Greenberg, R. & Laurence, L. (1981). A comparison of MMPI results for psychiatric patients and male applicants for transsexual surgery. *Journal of Nervous and Mental Disease* 169(5): 320-323.

Hare, L., Bernard, P., Sanchez, F. et al (2009). Androgen receptor length polymorphism associated with male-to-female transsexualism. *Biological Psychiatry* 65(1): 93-96.

Haas, A., Rodgers, P., Herman, J. (2014). Suicide Attempts among Transgender and Gender Non-Conforming Adults, *American Foundation for Suicide Prevention*.

Hatzenbuehler, M., Bellatorre, A., Lee, Y., et al (2014). Structural stigma and all-cause mortality in sexual minority populations. *Social Science and Medicine* 103: 33-41.

Hembree, W., Cohen-Kettenis, P., Delemarre-van de Waal, H. Goorin, L., Meyer, W., Spack, N., Montori, V. (2009). Endocrine treatment of transsexual persons: An endocrine society clinical practice guideline. *Journal of Clinical Endocrinology and Metabolism* 94(9), 3132-3154.

Hembre, W. et al (2017). Endocrine treatment of gender-dysphoric/gender incongruent persons: an endocrine society clinical practice guideline. *Journal of Clinical Endocrinology and Metabolism* 102(11), 3869-3903.

Hepp, U., Klaghofer, R., Burkhard-Kubler, R., Buddeberg, C. (2002). Treatment follow-up of transsexual patients: A catamnestic study. *Nervenarzt* 73(3): 283-288.

Henningsson, S., Westberg, L, Nilsson, S. et al (2005). Sex steroid-related genes and male-to-female transsexualism. *Psychoneuroendocrinology* 30(7): 657-664.

Horbach, S. et al (2015). Outcome of vaginoplasty in male-to-female transgenders: A systematic review of surgical techniques. *Journal of Sexual Medicine* 12(6): 1499-512.

Imbimbo, C. (2009). A report from a single institute's 14-year experience in treatment of male-female transsexuals. *Journal of Sexual Medicine*, 6(10): 2736-45.

Jarolim, L. et al. (2009). Gender reassignment surgery in male-to-female transsexualism: A retrospective 3-month follow-up study with anatomical remarks. *Journal of Sexual Medicine*, 6(6): 1635-44.

Johansson, A., Sundbom, E., Hojerback, T. & Bodlund, O. (2010). A five-year follow up study of Swedish adults with gender identity disorder. *Archives of Sexual Behavior*, 39(6): 1429-37.

Jokic-Begic, N., Korajlija, A., & Jurin, T. (2014). Psychosocial adjustment to sex reassignment surgery: A qualitative examination and personal experiences of six transsexual persons in Croatia. *The Scientific World Journal*: 2014.

Klein, C & Gorzalka, B. (2009). Sexual functioning in transsexuals following hormone therapy and genital surgery: A review. *Journal of Sexual Medicine* 6(11): 2922-2939.

Kockott, G., & Fahrner, E. (1987). Transsexuals who have not undergone surgery: A follow-up study. *Archives of Sexual Behavior* 16(6): 511-522.

Landen, M., Bodlund, O. Ekselius, L., Hambert, G., & Lundstrom, B. (2001). Done is done-and gone is gone: Sex reassignment is presently the best cure for transsexualism. *Lakartidningen* 98(30-31): 3322-26.

Lane, M. et al. (2018). Trends in gender-affirming surgery in insured patients in the United States. *PRS Global Open*.

Lawrence, A. (2003). Factors associated with satisfaction or regret following male-to-female sex reassignment surgery. *Archives of Sexual Behavior* 32(4): 299-315.

Lawrence, A. (2005). Sexuality before and after male-to-female sex reassignment surgery. *Archives of Sexual Behavior*, 34: 147-66.

Lawrence, A. (2006). Patient-reported complications and functional outcomes of male-to-female reassignment surgery. *Archives of Sexual Behavior* 35(6): 717-27.

Lindqvist, E., et al. (2017). Quality of life improves early after gender reassignment surgery in transgender women, *European Journal of Plastic Surgery* 40(3): 223-226.

Lobato, M. et al. (2006). Follow-up of sex reassignment surgery in transsexuals: A Brazilian cohort. *Archives of Sexual Behavior* 33: 711-15.

Longo, M., Azanon, E. & Haggard, P. (2010). More than skin deep: body representation beyond primary somatosensory cortex. *Neuropsychologia* 48: 665-668.

Luders, E., Narr, K., Thompson, P., Rex, D. et al (2006). Gender effects on cortical thickness and the influence of scaling. *Human Brain Mapping* 27: 314-324.

Matt-Kole, C., Freschi, M., & Robin, A. (1990). A controlled study of psychological and social change after surgical gender reassignment in selected male transsexuals. *British Journal of Psychiatry* 157, 261-264.

Monstrey, S., De Cuypere, G., & Ettner, R. (2007). Surgery: General principles. In Ettner, R., Monstrey, S., Eyler, A. (eds). <u>Principles of Transgender Medicine and Surgery</u> New York: Haworth Press.

Murad, M. et al (2010). Hormonal therapy and sex reassignment: a systematic review and meta-analysis of quality of life and psychosocial outcomes, Clinical Endocrinology 72(2): 214-31.

NCCHC Policy Statement, Transgender Health Care in Correctional Settings. (October 18, 2009).

Newfield, E., Hart, S., Dibble, S. & Kohler, L. (2006). Female-to-male transgender quality of life. *Quality of Life Research* 15(9) 1447-1457.

Nuttbrock, L, Rosenblum, A. & Blumenstein, R. (2002). Transgender identity affirmation and mental health. *International Journal of Transgenderism* 6(4).

Ohashi, K., Anderson, C., Bolder, E., et al (2017). Childhood maltreatment is associated with alteration in global network fiber-tract architecture independent of history of depression and anxiety. *Neuroimage* 150: 50-59.

Pauly, I. (1992). Terminology and classification of gender identity disorders. In Bockting & Coleman (eds.) <u>Gender Dysphoria: Interdisciplinary Approaches in Clinical Management.</u> New York: Haworth.

Padula, W. et al. (2015). Societal implications of health insurance coverage for medically necessary services in the U.S. transgender population: a cost effective analysis. *Journal of Internal Medicine*, 31(4): 394-401.

Pfafflin, F, & Junge, A. (1998). Sex reassignment: Thirty years of international follow-up studies after sex reassignment surgery, a comprehensive review, 1961-1991. (Jacobson & Meir, trans.).

Rametti, G., Carillo, B., Gomez-Gil, E., Junque, C. et al (2011). White matter microstructure in female to male transsexuals before cross-sex hormonal treatment: A diffusion tensor imaging study. *Journal of Psychiatric Research* 45:199-204.

Rehman, J., Lazer, S., Benet, A., Schaefer, L. & Melman, A. (1999). The reported sex and surgery satisfactions of 28 postoperative male-to-female transsexual patients. *Archives of Sexual Behavior* 28(1): 71-89.

Ruppin, U., Pfafflin, F. (2015). Long-term follow-up of adults with Gender Identity disorder, *Archives of Sexual Behavior* 44(5): 1321-1329.

Salim ,A., Poh, M. (2018). Gender affirming penile inversion vaginoplasty, *Clinics in Plastic Surgery* 45(3): 343-350.

Savic, I. & Arver, S. (2011). Sex dimorphism of the brain in male-to-female transsexuals. *Cerebral Cortex* 23: 2855-2862.

Schaefer, A. et al. (2016). Assessing the implications of allowing transgender personnel to serve openly, Rand Corporation.

Schneider, H., Pickel, J., Stalla, G. (2006). Typical female 2<sup>nd</sup> - 4<sup>th</sup> finger length (2D:4D) ratios in male-to-female transsexuals-possible implications for prenatal androgen exposure. *Psychoneuroendocrinology* 31(2):265-269.

Shaw, P., Kabani, N., Lerch, J. Eckstrand, K. et al. (2008). Neurodevelopmental trajectories of the human cerebral cortex. *Journal of Neuroscience* 28: 3586-3594.

Singh, A., Hays, D. & Watson (2011). Strengths in the face of adversity: Resilience strategies of transgender individuals. *Journal of Counseling and Development* 89(1): 20-27.

Smith, Y., Van Goozen, S., Kuiper, A., & Cohen-Kettenis, P. (2005). Sex reassignment: Outcomes and predictors of treatment for adolescent and adult transsexuals. *Psychological Medicine* 35(1): 89-99.

Spehr, C. (2007). Male to female sex reassignment surgery in transsexuals. *International Journal of Transgenderism* 10(1): 25-37.

Taziaux, M., Swaab, D., Bakker, J. (2012). Sex differences in the neurokin B system in the human infundibular nucleus. *Journal of Clinical Endocrinology and Metabolism* 97(12) 2010-2020.

Teicher, M., Samson, J., Sheu, Y., et al (2010). Hurtful words: Exposure to peer verbal aggression is associated with elevated psychiatric symptom scores and corpus callosum abnormalities. *American Journal of Psychiatry* 167(12): 1464-1471.

Van de Grift, T. et al (2017). Surgical satisfaction, quality of life, and their association after gender-affirming surgery: a follow-up study, *Journal of Sex & Marital Therapy* 44(2): 138-148.

Vujovic, S., Popovic, S., Sbutega-Milosevic, G., Djordjevic, M., & Gooren, L. (2009). Transsexualism in Serbia: A twenty-year follow-up study. *The Journal of Sexual Medicine* 6(4): 1018-1023.

Weyers, S. et al. (2009). Long-term assessments of the physical, mental and sexual health among transsexual women. *Journal of Sexual Medicine* 6(3): 752-60.

Whittle, S. et al. (2008). Medical necessity statement: WPATH clarification on medical necessity of treatment, sex reassignment, and insurance coverage in the U.S.A.

Wiepjes, C. et al (2018). The Amsterdam cohort of Gender Dysphoria study, *Journal of Sexual Medicine* 15(4): 582-590.

World Health Organization (1992). <u>International Classification of Diseases</u>, 10<sup>th</sup> ed.

World Professional Association for Transgender Health (2016). Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.

World Professional Association for Transgender Health, <u>Standards of Care for the Health of Transsexual</u>, <u>Transgender</u>, and <u>Gender-Nonconforming People</u>, 7<sup>th</sup> version (2012).

Yuksel, S., et al. (2017). Effects of gender reassignment on quality of life and mental health in people with gender dysphoria, *Turkish Journal of Psychiatry* 29(1): 11-21.

Zhou, J., Hofman, M., Gooren, L., et al (1995). A sex difference in the human brain and its relation to transsexuality. *Nature* 378(6552): 68-70.

Zubiaurre-Elorza, L., Junque, C., Gomez-Gil, E. & Guillamon, A. (2014). Effects of cross-sex hormone treatment on cortical thickness in transsexual individuals. *Journal of Sexual Medicine* 11: 1248-1261.