XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, **v.** **ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,** Defendants,	4:19-cv-02769-HSG **DECLARATION OF FRANCES PARMELEE IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** Date: October 10, 2019 Time: 2:00 P.M. Dept: 2, 4th Floor Judge: The Honorable Haywood S. Gilliam, Jr. Trial Date: Not set Action Filed: May 21, 2019

I, Frances Parmelee, declare:

1. I have served as the Assistant Vice Chancellor of College Finance and Facilities Planning Division with the California Community Colleges (CCC) since September 2016. In this role, I oversee and support the Budget Unit, Fiscal Services Unit, Fiscal Standards and Accountability Unit, and Facilities Planning Unit. Prior to joining the Chancellor's Office, I worked as an auditor, audit supervisor and audit manager with the Department of Finance for more than two decades. During this time, I led teams on a variety of financial and performance

audits, as well as organization-wide professional development activities. I earned a Bachelor of Science degree in Business Administration, Accounting and Finance from California State University, Sacramento and am an active CPA.

2. The California Community Colleges (CCC) is the largest system of higher education in the nation, with 2.1 million students attending 115 colleges. With a wide range of educational offerings, the colleges provide workforce training, basic courses in English and math, certificate and degree programs and preparation for transfer to four-year institutions. The colleges thus play a critical rule in the state's public education system.

3. I am familiar with the final rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the Rule), published in the Federal Register on May 21, 2019.

4. The Rule places at risk federal funds CCC receives from the U.S. Department of Health and Human Services, the U.S. Department of Education, and the U.S. Department of Labor, if California is determined to be in violation of the Rule.

5. Federal funding comes to CCC from appropriations acts approved by Congress and signed by the president. The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115-245, which was enacted September 28, 2019, makes appropriations that provide funding to CCC. In fiscal year 2018-2019, CCC received $83.4 million which may be at risk.

6. The following funding sources are at risk:

a. CalWORKs Services. These funds are 0.14% of the overall budget and used for the purpose of assisting welfare recipient students and those in transition off of welfare to achieve long-term self-sufficiency through coordinated student services offered at community colleges including: work study, job placement, child care, coordination, curriculum development and redesign, and under certain conditions post-employment skills training, and instructional services.

b. Foster Care Education Program. These funds are 0.11% of the overall budget and used for provide quality education and support opportunities to caregivers of children and youth in out-of-home care so that these providers may meet the educational, emotional, behavioral and developmental needs of children and youth in the foster care system.

c. Vocational Education. These funds are 1.15% of the overall budget and is aimed at increasing the quality of career technical education statewide.

7. In developing its budget, CCC does so in the expectation that it will receive the federal funds placed at risk under the rule, to which it is entitled under agreements with federal agencies. A sudden disruption in anticipated federal funds would cause budgetary and operational chaos.

8. Loss of federal funding will have a deleterious impact on CCC. CCC will be unable to absorb such a large loss of funding without reducing staffing, programs, and services.

9. If CCC were to lose federal funding, students who rely on CalWORKS services, the Foster Care Education Program, and our Vocational Education programs would be impacted and would be less able to receive a quality education.

10. The Rule may also necessitate programmatic changes. For example, some colleges have a pre-nursing program requirement that states that all incoming nursing students need to have completed a series of immunizations/vaccinations (including some vaccinations that the Rule appears to call into question, including MMR (Measles, Mumps & Rubella), Polio, and Varicella (chicken pox). If the community college has a course for pre-med or pre-nursing students wherein the students would be required to do training on vaccines or some other "procedure" that he/she finds objectionable, then the college could not require that the student "assist in the performance" of that procedure. The colleges would need to make changes to their programs to account for such refusals.

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I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on May 30, 2019 in Sacramento, CA.

Frances Parmelee
Assistant Vice Chancellor
California Community Colleges

XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,

Defendants,

4:19-cv-02769-HSG

DECLARATION OF DENISE PINES IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Date:	October 10, 2019
Time:	2:00 P.M.
Dept:	2, 4th Floor
Judge:	The Honorable Haywood S. Gilliam, Jr.
Trial Date:	Not set
Action Filed:	May 21, 2019

I, DENISE PINES, declare:

1. I am the President of the Medical Board of California (Board). I was appointed as a public member to the Board by Governor Edmund Gerald Brown, Jr., on August 29, 2012, and was elected President of the Board on July 26, 2018. I make this declaration in my official capacity as President of the Board and make this declaration of my own personal knowledge.

2. The Board is a state governmental agency established to protect the public by regulating the practice of physicians and surgeons and certain allied health care professionals,

including licensed midwives; it is a component of the California Department of Consumer Affairs. Cal. Bus. & Prof. Code §§ 101, 2004. The Board is responsible for the implementation and enforcement of the Medical Practice Act, the state laws related to medical education, licensure, practice, and discipline. Cal. Bus. & Prof. Code § 2000 *et seq*. The Board's authorizing statutes designate its highest priority as the protection of the public. Cal. Bus. & Prof. Code § 2001.1.

3. The Board's enforcement statute, California Business and Professions Code section 2234, directs that the Board shall take action against any licensee who is charged with unprofessional conduct. Unprofessional conduct under California Business and Professions Code section 2234 is conduct which breaches the rules or ethical code of the medical profession, or conduct which is unbecoming a member in good standing of the medical profession, and which demonstrates an unfitness to practice medicine. *Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 575.

4. To carry out its mission of protecting the public, the Board performs a number of functions, including but not limited to:

a. Evaluating licensure applications to determine whether the applicant meets the criteria for licensure;

b. Enforcing state law by taking appropriate disciplinary action against physicians and surgeons and other allied health care professionals who violate the Medical Practice Act; and

c. Adopting regulations and guidance to clarify the performance, practice, and disciplinary standards for its licensees.

5. The Board is mandated to protect consumers from licensees who practice in a manner that may be unsafe or unprofessional. The Board has authority to revoke, suspend, or place on probation any license if the licensee has violated a provision of the law governing the profession. Cal. Bus. & Prof. Code § 2220.

6. Physicians and surgeons and licensed midwives have a duty to obtain informed consent of patients before performing or ordering a procedure or treatment for which informed consent is required. See, e.g., 22 Cal. Code of Regs. § 72528.

7. The Board has a statutory responsibility to discipline a licensee if, because of a characteristic protected by California's Unruh Civil Rights Act, the licensee refuses to perform the licensed activity, if the licensee incites another licensee to refuse to perform the licensed activity, or if the licensee makes any discrimination or restriction in performing the licensed activity. Cal. Bus. & Prof. Code § 125.6(a)(1). Characteristics protected under the Unruh Civil Rights Act are sex, race, color, religion, ancestry, national origin, disability, medical condition, genetic information, marital status, sexual orientation, citizenship, primary language, and immigration status. Cal. Civ. Code § 51(b). "Sex" is defined to include, but not be limited to, gender, gender identity, gender expression, pregnancy, childbirth, and medical conditions related to pregnancy or childbirth. Cal Civ. Code § 51(e)(5).

8. I am familiar with the final rule Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, RIN 0945-AA10, issued by the U.S. Department of Health and Human Services and published in the Federal Register on May 21, 2019 (the Rule).

9. The Rule creates a broad exemption for medical professionals and personnel to opt out of any healthcare service based on a moral or religious ground. Specific scenarios are included in the Rule, including abortion, sterilization, euthanasia, certain vaccinations if there is an "aborted fetal tissue" connection (rubella, polio, Hep A, chickenpox, small pox), contraception, gender transition/gender dysphoria (counseling, administering hormone prescriptions, etc.), tubal ligations, hysterectomies, assisted suicide, and referrals for advanced directives.

10. Under the Rule, there is not any exception provided for emergency situations. This is notable because even in the exercise of a physician's conscience, "[p]hysicians are expected to provide care in emergencies, honor patients' informed decisions to refuse life-sustaining treatment, and respect basic civil liberties and not discriminate against individuals in deciding whether to enter into a professional relationship with a new patient." American Medical

Association, Policy E-1.1.7, "Physician Exercise of Conscience." Code of Medical Ethics. Adopted 2016. *See also* Cal. Health & Saf. Code § 123420(d) (stating that California's abortion conscience refusal law does not apply to medical emergency situations and spontaneous abortions); Cal. Health & Saf. Code § 1317 (a) & (e) (requiring that any health facility that operates an emergency department provide emergency services to patients for any condition in which the person is in danger of loss of life, or serious injury or illness); *see also* 42 U.S.C. § 1395dd(a).

11. Under the Rule, physicians and surgeons can refuse medical care without any information about the patient's medical condition or treatment options, not just on the basis of federally protected conscience protections, but also on the basis of "ethical or other reasons." A provider can do this without any supporting evidence, without notifying a supervisor of the denial of service, even in emergency situations, and without providing notice or alternative options and/or referrals to patients in need.

12. The Rule if implemented may thus impact the work and mission of the Board.

13. If, as a result of the Rule's requirements, patients file complaints against physicians and surgeons who deny care or fail to provide them with timely, accurate, and complete information, or if there is a complaint of denial of care due to an allegation of discrimination, then the Board will have to investigate such complaints.

14. Furthermore, the Board is responsible for enforcing California law through disciplinary proceedings. Thus, the Board may face an increase in disciplinary matters for physicians and surgeons if these complaints are substantiated.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on June 3, 2019, in Los Angeles, CA

Denise Pines
President
Medical Board of California

XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, **v.** **ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,** Defendants,	4: 19-cv-02769-HSG **DECLARATION OF STIRLING PRICE IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** Date: October 10, 2019 Time: 2:00 P.M. Dept: 2, 4th Floor Judge: The Honorable Haywood S. Gilliam, Jr. Trial Date: Not set Action Filed: May 21, 2019

I, Stirling Price, declare:

1. The matters stated in this declaration are true based upon my own personal knowledge, except as to those matters stated on information and belief, and as to those matters, I believe them to be true, and if called as a witness, I would competently so testify.

2. I am employed by the California Department of State Hospitals (DSH). Since my appointment in September 2018, I have been the DSH Chief Deputy Director (A). I report to the Director of the Department of State Hospitals. In my position as the Chief Deputy Director of

DSH, my duties include briefing the Director on any significant matters pertaining to DSH. As the Acting Chief Deputy Director, five executive directors of the five state hospitals report to me. In addition, the deputy directors of the following DSH's divisions report to me: Legal, Forensic Services, Statewide Quality Improvement, Hospital Strategic Planning and Implementation, Administrative Services, Clinical Operations, Office of Protective Services and Technology Services. My current duties as the Chief Deputy Director include the following: I attend all the DSH executive team meetings regarding DSH policy and procedures. I am involved in DSH matters concerning the Health and Human Services Agency, other DSH control agencies, and public and private stakeholders. I also attend budget hearings before the state legislature.

3. Prior to being appointed as DSH's Acting Chief Deputy Director, I was the Executive Director of DSH-Atascadero. I was in this position from January 1, 2015 to August 31, 2018. Prior to working at DSH-Atascadero, I was the interim Deputy Director, Forensic Services. Prior to that, I was the Executive Director for DSH-Stockton. I was in this position when the hospital opened on July 22, 2013. This facility is now under the jurisdiction of the California Department of Corrections and Rehabilitation (CDCR). Prior to working at DSH-Stockton, in 2011 I was the Executive Director at the DSH-Vacaville Psychiatric Program and the acting Executive Director at DSH-Salinas Valley Psychiatric Program, both of which are currently under the jurisdiction of CDCR. In May 1981, I earned an Associate of Arts degree from Los Angeles Valley College. In May 1989, I earned a Bachelor of Arts Degree from California State University, Sacramento. In May 1991, I earned a Master's Degree in Social Work from California State University, Sacramento. In 1994, I became a California Licensed Clinical Social Worker (LCSW).

4. DSH is one of 16 departments and offices in the California Health and Human Services Agency. DSH manages the California state hospital system, which provides mental health services to patients admitted into DSH facilities. The department strives to provide effective treatment in a safe environment and in a fiscally responsible manner. DSH oversees five state hospitals: Atascadero, Coalinga, Metropolitan (in Los Angeles County), Napa and

Patton. As of 2018, the department employs more than 11,000 staff and serves more than 12,000 patients annually in a 24/7 hospital system.

5. In the last ten years, the population demographics of DSH has shifted from fewer civil court commitments to primarily a forensic population committed through the criminal court system. Approximately 91 percent of the patient population is forensic. The remaining 9% are patients admitted in accordance with the Lanterman-Petris-Short (LPS) Act (mental health confinements).

6. I am familiar with the rule, Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, RIN 0945-AA10, issued by the U.S. Department of Health and Human Services (HHS) on May 2, 2019 (Rule), and published in the Federal Register on May 21, 2019.

7. The Rule will impose an immediate cost on DSH due to its notice, assurance and certification, recordkeeping, and reporting requirements. The Rule has already imposed costs on DSH as DSH has been required to spend approximately fifteen hours reading and analyzing the Rule, and attempting to determine its impact on DSH programs and whether programmatic changes are necessitated.

8. The Rule creates a broad exemption for medical professionals and personnel to opt out of healthcare services based on a moral or religious ground. Specifically, personnel may opt out of healthcare services involving abortion, sterilization, and euthanasia. Further, the rule appears to enable objections to providing a broad range of healthcare services, including certain vaccinations if there is an "aborted fetal tissue" connection (rubella, polio, Hep A, chickenpox, small pox), contraception, gender transition/gender dysphoria (counseling, administering hormone prescriptions, etc.), tubal ligations, hysterectomies, and assisted suicide. There does not appear to be any exception provided for emergency situations under the Rule.

9. DSH does not deny medically necessary care for its patients. Thus as a result of the Rule, DSH would be required to adopt a Policy Directive that would enforce the patient's legal right to necessary medical treatment (even though it may be against an employee's religious beliefs). Specifically, the policy would state that any legally and medically required service with patient consent or a court order, shall be provided by DSH staff or DSH contractors.

10. Currently, if staff were to refuse to perform work due to a religious belief, substitute staff is brought in to perform the objected-to service. But the Rule expands the scope of objections that can be made to include objections on the basis of "conscience, religious beliefs, or moral convictions" to not just services such as abortion, sterilization, and euthanasia (none of which DSH performs), but also "other health services." 84 Fed. Reg. 23170, 23228. And the Rule will be unworkable if it permits a medical provider to refuse "other health services" without notifying a supervisor of the denial of service, or without providing notice or alternative options and/or referrals to patients.

11. The notification provision of the Rule will impose costs on DSH. Although the Rule indicates that the notice provisions are now voluntary (unlike in the proposed rule), the Rule also states that adherence to the notice provisions will be taken into consideration when assessing whether an agency is in compliance. To provide notice, DHS will need to: (1) post the notice in Appendix A (or similar text) at each DSH establishment where notices to the public and workforce are customarily posted, and thereafter continuously take steps to ensure that the notice is not altered, defaced, or covered by other materials, (2) include the notice on each of its websites, and (3) include the notice in its personnel manuals, applications, and benefits and training materials, as inclusion in these materials will be a factor in determining whether DSH is in compliance. The estimated costs of compliance with these notification provisions is approximately $600 per hospital, due to the necessary changes to websites, physical postings at all five hospitals and administrative facilities, as well as costs associated with updates to training manuals, new employee documentation, internship materials, and updates to benefits handbooks.

12. The Rule will require DSH to create and draft a new policy in response to its requirements. DSH estimates the cost of creating this new policy at $2,000, taking into account preparation costs and legal review. In addition the Rule will require DSH legal staff to interpret and give advice, especially in the first year. DSH estimates costs of $4,000 for these services in the first year.

13. However, the aforementioned figures do not include costs that may be associated with the assurance, certification, and record-keeping requirements, to the extent that they apply,

that should be included with all applications, reapplications, and amendments and modifications. Notably, under the compliance provision, if a sub-recipient (as defined by the Rule) is found in violation, DSH will be subject to remedial action. This Rule thus places some oversight obligation on DSH which could result in additional staffing costs to engage in this sub-recipient monitoring component. This is significant because DSH contracts out for several health services for its patients to off-site entities.

14. The Rule places at risk federal funds DSH receives from the U.S. Department of Health and Human Services. In fiscal year 2017-2018, DSH received $4.6 million in Medicare revenue; only about $429,000 of this was Medicare Part B funding and not considered Federal Financial Assistance under the Rule. Loss of approximately $4.2 million of federal funding would have a grave impact on DSH operations and its ability to continue to provide services to its population. DSH would be unable to absorb such a large loss of funding without a reduction in staffing and services.

15. On the contrary, DSH already operates under a constrained budget and continues to seek solutions to address the significant growth in its patient population. As of December 31, 2018, DSH has a total of 1,101 patients pending placement, of which 815 are Incompetent to Stand Trial (IST). DSH continues to explore alternatives both in the state hospitals and through contracted facilities to address the waitlist. Thus, a loss of funding in the magnitude of $4.2 million (either because it, a sub-recipient, or another California agency is found in violation) would only further diminish DSH's ability to serve its population.

16. In developing its annual budget, DSH did so with the expectation that it would receive the federal funds which are put at risk under the Rule, and to which it is entitled to under its agreements with federal agencies.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on May 28, 2019 in Sacramento, CA.

Stirling Price
Chief Deputy Director (A)
California Department of State Hospitals

XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,

Defendants,

4:19-cv-02769-HSG

DECLARATION OF JAY STURGES IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Date:	October 10, 2019
Time:	2:00 P.M.
Dept:	2, 4th Floor
Judge:	The Honorable Haywood S. Gilliam, Jr.
Trial Date:	Not set
Action Filed:	May 21, 2019

I, Jay Sturges, declare:

1. I am the Associate Secretary, Fiscal Policy and Administration, for the California Labor and Workforce Development Agency (LWDA). I serve as the primary advisor to the Agency Secretary on the interpretation, development, evaluation and implementation of Agency-level fiscal policies and for ensuring the fiscal integrity of the departments, boards and panels within the LWDA.

2. The LWDA is an agency in the executive branch, and the Secretary is a member of the Governor's Cabinet. LWDA oversees seven major departments, boards and panels that serve California businesses and workers: the Agricultural Labor Relations Board, the California Employment Development Department, the California Public Employment Relations Board, the California Unemployment Insurance Appeals Board, the California Workforce Development Board, the Department of Industrial Relations, and the Employment Training Panel. LWDA programs and services touch the lives of all members of the state's workforce and their families.

3. I am familiar with the rule Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, RIN 0945-AA10, issued by the U.S. Department of Health and Human Services (HHS) on May 2, 2019, and published in the Federal Register on May 21, 2019 (the Rule).

4. The Rule has already imposed costs on California. LWDA and the departments within the agency have already spent more than 11 hours reading and analyzing the Rule and attempting to determine its potential impacts on our programs and workforce.

5. The Rule jeopardizes federal funds departments within the LWDA receive from the U.S. Department of Labor, if California is determined to violate the Rule. Loss of federal funding will have a deleterious impact on California, the nation's most populous state, by hampering workplace safety, stifling economic development, and harming efforts to assist unemployed individuals. LWDA and the departments and offices it oversees will be unable to absorb such a tremendous loss of funding without a reduction in staffing, programs and services.

6. In developing the state's annual budget, the departments within the LWDA did so with the expectation that they would receive the federal funds placed at risk under the Rule, and to which they are entitled to under agreements with federal agencies. A sudden disruption in anticipated federal funds would create budgetary and operational chaos.

7. Federal funding comes to the departments within the LWDA from appropriations acts approved by Congress and signed by the president. The Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115-245, which was enacted September 28, 2019, makes appropriations

for the following programs (among others), which provide funding to the departments within the LWDA:

- Title III of the Social Security Act, (the State Unemployment Insurance Program), to provide payments to laid-off workers;
- The Workforce Innovation and Opportunity Act, including grants to states for adult employment and training activities, youth activities, and dislocated worker employment and training activities;
- The Wagner-Peyser Act of 1933 to establish a nationwide system of public employment offices to assist individuals seeking employment;
- The Occupational Safety and Health Act, section 23(g), to assist states in administering and enforcing programs for occupational safety and health;
- The Jobs for Veterans State grants program under 38 U.S.C. 4102A(b)(5) to support disabled veterans' outreach program specialists; and
- The National Apprenticeship Act to expand apprenticeship and on-the-job training programs.

8. Federal funding supports numerous programs within the LWDA, including dollars that support state operations or are passed through to local workforce development boards. With regard to the programs within LWDA (among others) that are jeopardized by the Rule, the state's 2019-20 Governor's Budget anticipates receiving federal funding in state fiscal year 2018-19 for the following programs:

- The California Employment Development Department provides short-term income replacement for individuals who are unemployed through no fault of their own through the administration of the Unemployment Insurance benefit payment program, allocates funding to local workforce development boards and provides direct services that benefit job seekers and employers statewide ($899.9 million);
- The California Unemployment Insurance Appeals Board conducts impartial hearings and issues decisions to resolve disputed unemployment insurance determinations ($66.5 million);

- The California Workforce Development Board, which collaborates with both state and local partners to establish and continuously improve the state workforce system, with an emphasis on California's economic vitality and growth ($4.8 million);
- The Department of Industrial Relations (DIR), which is responsible for enforcing workers' compensation insurance laws, adjudicating workers' compensation claims, and working to prevent industrial injuries and deaths, as well as promulgating regulations and enforcing laws relating to wages, hours, and conditions of employment, promoting apprenticeship and other on-the-job training, and analyzing and disseminating statistics which measure the condition of labor in the state ($38.3 million);

9. Within DIR, federal funding supports numerous programs and subprograms, including the following:

- The Division of Occupational Safety and Health, which promotes and enforces measures to protect the health and safety of workers on the job and the safe operation of elevators, amusement rides, aerial passenger tramways, and pressure vessels for the benefit of the general public, is authorized through the state budget to receive a total of $36.4 million in federal funding in 2018-19. This supports the Compliance subprogram ($25.9 million), the Mining and Tunneling subprogram ($433,000), the Occupational Safety and Health Appeals Board ($2.3 million), the Occupational Safety and Health Standards Board ($1.2 million), and Consultation Services ($6.6 million);
- The Division of Labor Standards Enforcement, for the Retaliation subprogram ($504,000); and
- The Division of Apprenticeship Standards, to increase the number of apprenticeships in California ($1.4 million).

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I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on May 22, 2019 in Sacramento, California.

Jay Sturges
Associate Secretary, Fiscal Policy and Administration
California Labor & Workforce Development Agency

XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, **v.** **ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,** Defendants,	4:19-cv-02769-HSG **DECLARATION OF DIANA TOCHE, D.D.S., IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** Date: October 10, 2019 Time: 2:00 P.M. Dept: 2, 4th Floor Judge: The Honorable Haywood S. Gilliam, Jr. Trial Date: Not set Action Filed: May 21, 2019

I, Diana Toche, D.D.S., declare:

1. The matters stated in this declaration are true based on my own personal knowledge, except as to those matters stated on information and belief, and as to those matters, I believe them to be true, and if called as a witness, I would competently so testify.

2. I am the Undersecretary for Health Care Services, California Department of Corrections and Rehabilitation (CDCR) and have been serving in this capacity since May 13, 2014. Previously, I served CDCR as the Acting Undersecretary for Administration and Offender

Services, Acting Director of the Division of Health Care Services and Deputy Director, Division of Health Care Services, Dental Programs. Some of my current duties as Undersecretary for Health Care Services include directing the management and supervision of medical, mental health, dental and ancillary health care services for inmates under the jurisdiction of CDCR.

3. In conjunction with Clark Kelso, the federal Receiver appointed under the federal class action of *Plata v. Brown*, I lead California Correctional Health Care Services (CCHCS), the state entity responsible for providing health care services to CDCR's adult prison population. The CCHCS provides medical, dental, and mental health care services to California's prison inmate population of approximately 129,000 in 35 CDCR institutions and contracted facilities. It is also responsible for monitoring and directing the care for about 4000 inmates at CDCR's contracted facilities. CCHCS has almost 18,000 state civil service positions authorized in Fiscal Year 2018-2019, primarily located at the 35 prisons, at its headquarters in Elk Grove, California, and at CDCR headquarters in Sacramento, California. In addition to state funding, CCHCS is eligible to receive federal Medicaid funds for the inpatient hospitalization of some inmates through the California Department of Health Care Service Medi-Cal program, pursuant to California Penal Code sections 5072 and 2065.

4. I am familiar with the rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," RIN 0945-AA10, issued by the U.S. Department of Health and Human Services (the Rule), published in the Federal Register on May 21, 2019.

5. The Rule will impose an immediate cost on CCHCS due to its notice, assurance and certification, recordkeeping, and reporting requirements. The Rule has already imposed costs on CCHCS as CCHCS has been required to spend twenty hours reading and analyzing the Rule, and attempting to determine its impact on CCHCS programs and whether programmatic changes are necessitated.

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6. The Rule allows health care staff and ancillary personnel to refuse to provide care on religious or moral grounds for wide range of services, including but not limited to abortion, sterilization and euthanasia. Objections could apparently also impact providing vaccinations, treatment for gender dysphoria and delivering end-of-life care.

7. CCHCS was established in order for the state to better coordinate its continuing remedial efforts with those of the court-appointed Receiver in the *Plata* case. Inmates in the custody of CDCR are entitled to receive medical, dental and mental health care in a nondiscriminatory and timely manner under both federal and state law. California Penal Code sections 3402 through 3409 mandate services for female inmates, including contraception, birth control and abortion. Under the Eighth and Fourteenth Amendments, CCHCS is obliged to provide transgender inmates with medical and mental health care services. As noted by the Supreme Court in *Brown v. Plata*, 563 U.S. 493 (2011), mental health and medical care in CDCR were determined to fall below Eighth Amendment standards in 1995 and 2001, respectively. Providing timely access to emergency, routine and specialty care and ensuring inmates receive competent, effective services as required for CCHCS and CDCR to comply with the continuing orders of the federal district court cases are key linchpins of CCHCS' efforts.

8. Ensuring there are sufficient numbers of providers, nurses and support staff available to provide inmate care within the California prison system and that they effectively coordinate with community specialty and hospital services are essential components of a constitutionally adequate correctional health care delivery system. In addition, custody and transportation staff must be available and ready to ensure security for in-prison care and especially for off-site services and hospitalizations. The Rule appears to allow a medical provider to deny care for an uncertain range of health services without providing notice or making alternative options available. It is not clear whether objections could be lodged by the correctional staff whose assistance is critical to the delivery of a contested medical service. Having to arrange for substituted provider staff and rescheduling appointments and transportation will increase risks in the delivery of inmate health care services. Delays by themselves can put CCHCS out of compliance with court orders. Additional staff and contractors will be added to

ensure sufficient redundant capabilities are available for unexpected objections to provide care. Modifications to workforce policies regarding the expected performance, procedures for conducting employee investigations and modifications to bargaining unit agreements are anticipated, particularly during the first year of the Rule.

9. The notification provisions of the Rule will impose further costs on CCHCS. Although the Rule indicates that the notice provisions are now voluntary (unlike in the proposed rule), the Rule also states that adherence to the notice provisions will be taken into consideration when assessing whether an agency is in compliance. To provide notice, CCHCS will need to: (1) post the notice in Appendix A (or similar text) at each CCHCS establishment where notices to the public and workforce are customarily posted, and thereafter continuously take steps to ensure that the notice is not altered, defaced, or covered by other materials, (2) include the notice on each of its websites, and (3) include the notice in its personnel manuals, applications, and benefits and training materials, as inclusion in these materials will be a factor in determining whether CCHCS is in compliance. The estimated costs of compliance with these notification provisions is approximately $10,000 due to the necessary changes to websites, physical postings at medical facilities and administrative facilities, as well as costs associated with updates to training manuals, new employee documentation, internship materials, and updates to benefits handbooks.

10. The Rule also includes an assurance and certification requirement that should be included with all applications, reapplications, and amendments and modifications. The provision also places an obligation on CCHCS to take actions to come into compliance. Notably and under the compliance provision, if a sub-recipient (as defined by the Rule) is found in violation, CCHCS will be subject to remedial action. The Rule requires CCHCS to undertake some additional oversight obligations regarding its hundreds of contracted health care providers working both within CDCR institutions and in the community which would require CCHCS to utilize additional staff time to perform this sub-recipient monitoring component.

11. In addition to responding to complaints and investigations, the compliance provision of the Rule includes a recordkeeping and reporting requirement applicable to all recipients and sub-recipients which obligates CCHCS to include information concerning any

compliance reviews or complaints to the Office of Civil Rights within the last five years as part of the application process. The costs of responding to any complaints and any resulting recordkeeping and reporting requirements is unknown but hard costs and staff time could be significant depending on the number of complaints submitted.

12. The Rule places at risk federal funds CCHCS receives from the U.S. Department of Health and Human Services. In the past two fiscal years, CCHCS has received over $89 million dollars from Medi-Cal, funds critically necessary to support the current level of care by civil service and contracted staff and facilities. The appointment of the federal Receiver was, in large part, due to the state's inability to adequately ensure a sufficient number of CDCR providers and arrange for an available network of community specialists and facilities. A loss of federal funding would materially undermine the efforts of CCHCS and CDCR to provide a constitutional level of health care for California inmates.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on June 4, 2019, in Sacramento, California.

Diana Toche DDS

Diana Toche, DDS
Undersecretary
California Department of Corrections and Rehabilitation

XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,

Defendants,

4:19-cv-02769-HSG

DECLARATION OF CHRISTOPHER M. ZAHN, MD IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Date:	October 10, 2019
Time:	2:00 P.M.
Dept:	2, 4th Floor
Judge:	The Honorable Haywood S. Gilliam, Jr.
Trial Date:	Not set
Action Filed:	May 21, 2019

I, Christopher M. Zahn, MD, declare:

1. I am the Vice President, Practice Activities at the American College of Obstetricians and Gynecologists (ACOG). I received my medical degree from Uniformed Services University of the Health Sciences and I am a retired Air Force Officer. Prior to working at ACOG, I was a Professor and Chair of Obstetrics and Gynecology at the Uniformed Services University of the Health Sciences (USUHS), and a staff physician in the Departments of

Obstetrics and Gynecology and Pathology at Walter Reed National Military Medical Center in Bethesda, Maryland.

2. ACOG is the specialty's premier professional membership organization dedicated to the improvement of women's health. With more than 58,000 members, the College is a 501(c)(6) organization and its activities include producing practice guidelines and other educational material.

3. ACOG periodically releases Committee Opinions. Committee Opinions represent an ACOG committee's assessment of emerging issues in obstetric and gynecologic practice and are reviewed regularly for accuracy.

4. ACOG Committee Opinion 385, "The Limits of Conscientious Refusal in Reproductive Medicine" was released by the ACOG Committee on Ethics in November 2007 and was reaffirmed in 2016. A true and correct copy of Committee Opinion 385 is attached as Exhibit A.

5. Per Committee Opinion 385, "[t]hose who choose the profession of medicine (like those who choose the profession of law or who are trustees) are bound by special *fiduciary duties*, which oblige physicians to act in good faith to protect patients' health—particularly to the extent that patients' health interests conflict with physicians' personal or self-interest." (Italics in original.)

6. Per Committee Opinion 385, "[p]roviding complete, scientifically accurate information about options for reproductive health, including contraception, sterilization, and abortion, is fundamental to respect for patient autonomy and forms the basis of informed decision making in reproductive medicine. Providers refusing to provide such information on the grounds of moral or religious objection fail in their fundamental duty to enable patients to make decisions for themselves."

7. Per Committee Opinion 385, "[p]atients rightly expect care guided by best evidence as well as information based on rigorous science. When conscientious refusals reflect a misunderstanding or mistrust of science, limits to conscientious refusal should be defined, in part, by the strength or weakness of the science on which refusals are based. In other words, claims of

conscientious refusal should be considered invalid when the rationale for a refusal contradicts the body of scientific evidence."

8. Per Committee Opinion 385, "[p]ersons intending conscientious refusal should consider the degree to which they create or reinforce an unfair distribution of the benefits of reproductive technology. For instance, refusal to dispense contraception may place a disproportionate burden on disenfranchised women in resource-poor areas. Whereas a single, affluent professional might experience such a refusal as inconvenient and seek out another physician, a young mother of three depending on public transportation might find such a refusal to be an insurmountable barrier to medication because other options are not realistically available to her. She thus may experience loss of control of her reproductive fate and quality of life for herself and her children. Refusals that unduly burden the most vulnerable of society violate the core commitment to justice in the distribution of health resources."

9. Per Committee Opinion 385, "[l]egitimizing refusals in reproductive contexts may reinforce the tendency to value women primarily with regard to their capacity for reproduction while ignoring their interests and rights as people more generally."

10. In Committee Opinion 385, the ACOG Committee on Ethics makes the recommendation that "[i]n the provision of reproductive services, the patient's well-being must be paramount. Any conscientious refusal that conflicts with a patient's well-being should be accommodated only if the primary duty to the patient can be fulfilled."

11. In Committee Opinion 385, the ACOG Committee on Ethics makes the recommendation that "[h]ealth care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care. They must disclose scientifically accurate and professionally accepted characterizations of reproductive health services."

12. In Committee Opinion 385, the ACOG Committee on Ethics makes the recommendation that "[w]here conscience implores physicians to deviate from standard practices, including abortion, sterilization, and provision of contraceptives, they must provide potential patients with accurate and prior notice of their personal moral commitments."

13. In Committee Opinion 385, the ACOG Committee on Ethics makes the recommendation that "[i]n an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections."

14. In Committee Opinion 385, the ACOG Committee on Ethics makes the recommendation that "[i]n resource-poor areas, access to safe and legal reproductive services should be maintained. Conscientious refusals that undermine access should raise significant caution."

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on 23rd of May, 2019 in Washington, DC.

Christopher M. Zahn, MD
Vice President, Practice Activities
American College of Obstetricians and Gynecologists

EXHIBIT A

ACOG COMMITTEE OPINION

Number 385 • November 2007

The Limits of Conscientious Refusal in Reproductive Medicine

Committee on Ethics

Reaffirmed 2016

ABSTRACT: Health care providers occasionally may find that providing indicated, even standard, care would present for them a personal moral problem—a conflict of conscience—particularly in the field of reproductive medicine. Although respect for conscience is important, conscientious refusals should be limited if they constitute an imposition of religious or moral beliefs on patients, negatively affect a patient's health, are based on scientific misinformation, or create or reinforce racial or socioeconomic inequalities. Conscientious refusals that conflict with patient well-being should be accommodated only if the primary duty to the patient can be fulfilled. All health care providers must provide accurate and unbiased information so that patients can make informed decisions. Where conscience implores physicians to deviate from standard practices, they must provide potential patients with accurate and prior notice of their personal moral commitments. 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. In resource-poor areas, access to safe and legal reproductive services should be maintained. Providers with moral or religious objections should either practice in proximity to individuals who do not share their views or ensure that referral processes are in place. In an emergency in which referral is not possible or might negatively have an impact on a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care.

Physicians and other providers may not always agree with the decisions patients make about their own health and health care. Such differences are expected—and, indeed, underlie the American model of informed consent and respect for patient autonomy. Occasionally, however, providers anticipate that providing indicated, even standard, care would present for them a personal moral problem—a conflict of conscience. In such cases, some providers claim a right to refuse to provide certain services, refuse to refer patients to another provider for these services, or even decline to inform patients of their existing options (1).

Conscientious refusals have been particularly widespread in the arena of reproductive medicine, in which there are deep divisions regarding the moral acceptability of pregnancy termination and contraception. In Texas, for example, a pharmacist rejected a rape victim's prescription for emergency contraception, arguing that dispensing the medication was a "violation of morals" (2). In Virginia, a 42-year-old mother of two was refused a prescription for emergency contraception, became pregnant, and ultimately underwent an abortion she tried to prevent by requesting emergency contraception (3). In California, a physician refused to perform intrauterine insemination for a lesbian couple, prompted by religious beliefs and disapproval of lesbians having children (4). In Nebraska, a 19-year-old woman with a life-threatening pulmonary embolism at 10 weeks of gestation was refused a first-trimester pregnancy termination when admitted to a religiously affiliated hospital and was ultimately transferred by ambulance to another facility to undergo the procedure (5). At the heart of each of these examples of refusal is a claim of conscience—a claim that to provide certain services would compromise the moral integrity of a provider or institution.

The American College of Obstetricians and Gynecologists
Women's Health Care Physicians

In this opinion, the American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics considers the issues raised by conscientious refusals in reproductive medicine and outlines a framework for defining the ethically appropriate limits of conscientious refusal in reproductive health contexts. The committee begins by offering a definition of conscience and describing what might constitute an authentic claim of conscience. Next, it discusses the limits of conscientious refusals, describing how claims of conscience should be weighed in the context of other values critical to the ethical provision of health care. It then outlines options for public policy regarding conscientious refusals in reproductive medicine. Finally, the committee proposes a series of recommendations that maximize accommodation of an individual's religious or moral beliefs while avoiding imposition of these beliefs on others or interfering with the safe, timely, and financially feasible access to reproductive health care that all women deserve.

Defining Conscience

In this effort to reconcile the sometimes competing demands of religious or moral freedom and reproductive rights, it is important to characterize what is meant by conscience. *Conscience* has been defined as the private, constant, ethically attuned part of the human character. It operates as an internal sanction that comes into play through critical reflection about a certain action or inaction (6). An appeal to conscience would express a sentiment such as "If I were to do 'x,' I could not live with myself/I would hate myself/I wouldn't be able to sleep at night." According to this definition, not to act in accordance with one's conscience is to betray oneself—to risk personal wholeness or identity. Thus, what is taken seriously and is the specific focus of this document is not simply a broad claim to provider autonomy (7), but rather the particular claim to a provider's right to protect his or her *moral integrity*—to uphold the "soundness, reliability, wholeness and integration of [one's] moral character" (8).

Personal conscience, so conceived, is not merely a source of potential conflict. Rather, it has a critical and useful place in the practice of medicine. In many cases, it can foster thoughtful, effective, and humane care. Ethical decision making in medicine often touches on individuals' deepest identity-conferring beliefs about the nature and meaning of creating and sustaining life (9). Yet, conscience also may conflict with professional and ethical standards and result in inefficiency, adverse outcomes, violation of patients' rights, and erosion of trust if, for example, one's conscience limits the information or care provided to a patient. Finding a balance between respect for conscience and other important values is critical to the ethical practice of medicine.

In some circumstances, respect for conscience must be weighed against respect for particular social values. Challenges to a health care professional's integrity may occur when a practitioner feels that actions required by an external authority violate the goals of medicine and his or her fiduciary obligations to the patient. Established clinical norms may come into conflict with guidelines imposed by law, regulation, or public policy. For example, policies that mandate physician reporting of undocumented patients to immigration authorities conflict with norms such as privacy and confidentiality and the primary principle of nonmaleficence that govern the provider–patient relationship (10). Such challenges to integrity can result in considerable moral distress for providers and are best met through organized advocacy on the part of professional organizations (11, 12). When threats to patient well-being and the health care professional's integrity are at issue, some individual providers find a conscience-based refusal to comply with policies and acceptance of any associated professional and personal consequences to be the only morally tenable course of action (10).

Claims of conscience are not always genuine. They may mask distaste for certain procedures, discriminatory attitudes, or other self-interested motives (13). Providers who decide not to perform abortions primarily because they find the procedure unpleasant or because they fear criticism from those in society who advocate against it do not have a genuine claim of conscience. Nor do providers who refuse to provide care for individuals because of fear of disease transmission to themselves or other patients. Positions that are merely self-protective do not constitute the basis for a genuine claim of conscience. Furthermore, the logic of conscience, as a form of self-reflection on and judgment about whether one's own acts are obligatory or prohibited, means that it would be odd or absurd to say "I would have a guilty conscience if she did 'x.'" Although some have raised concerns about complicity in the context of referral to another provider for requested medical care, the logic of conscience entails that to act in accordance with conscience, the provider need not rebuke other providers or obstruct them from performing an act (8). Finally, referral to another provider need not be conceptualized as a repudiation or compromise of one's own values, but instead can be seen as an acknowledgment of both the widespread and thoughtful disagreement among physicians and society at large and the moral sincerity of others with whom one disagrees (14).

The authenticity of conscience can be assessed through inquiry into 1) the extent to which the underlying values asserted constitute a core component of a provider's identity, 2) the depth of the provider's reflection on the issue at hand, and 3) the likelihood that the provider will experience guilt, shame, or loss of self-respect by performing the act in question (9). It is the genuine claim of conscience that is considered next, in the context of the values that guide ethical health care.

Defining Limits for Conscientious Refusal

Even when appeals to conscience are genuine, when a provider's moral integrity is truly at stake, there are clear-

ly limits to the degree to which appeals to conscience may justifiably guide decision making. Although respect for conscience is a value, it is only a prima facie value, which means it can and should be overridden in the interest of other moral obligations that outweigh it in a given circumstance. Professional ethics requires that health be delivered in a way that is respectful of patient autonomy, timely and effective, evidence based, and nondiscriminatory. By virtue of entering the profession of medicine, physicians accept a set of moral values—and duties—that are central to medical practice (15). Thus, with professional privileges come professional responsibilities to patients, which must precede a provider's personal interests (16). When conscientious refusals conflict with moral obligations that are central to the ethical practice of medicine, ethical care requires either that the physician provide care despite reservations or that there be resources in place to allow the patient to gain access to care in the presence of conscientious refusal. In the following sections, four criteria are highlighted as important in determining appropriate limits for conscientious refusal in reproductive health contexts.

1. Potential for Imposition

The first important consideration in defining limits for conscientious refusal is the degree to which a refusal constitutes an imposition on patients who do not share the objector's beliefs. One of the guiding principles in the practice of medicine is respect for patient autonomy, a principle that holds that persons should be free to choose and act without controlling constraints imposed by others. To respect a patient's autonomy is to respect her capacities and perspectives, including her right to hold certain views, make certain choices, and take certain actions based on personal values and beliefs (17). Respect involves acknowledging decision-making rights and acting in a way that enables patients to make choices for themselves. Respect for autonomy has particular importance in reproductive decision making, which involves private, personal, often pivotal decisions about sexuality and childbearing.

It is not uncommon for conscientious refusals to result in imposition of religious or moral beliefs on a patient who may not share these beliefs, which may undermine respect for patient autonomy. Women's informed requests for contraception or sterilization, for example, are an important expression of autonomous choice regarding reproductive decision making. Refusals to dispense contraception may constitute a failure to respect women's capacity to decide for themselves whether and under what circumstances to become pregnant.

Similar issues arise when patients are unable to obtain medication that has been prescribed by a physician. Although pharmacist conduct is beyond the scope of this document, refusals by other professionals can have an important impact on a physician's efforts to provide appropriate reproductive health care. Providing complete, scientifically accurate information about options for reproductive health, including contraception, sterilization, and abortion, is fundamental to respect for patient autonomy and forms the basis of informed decision making in reproductive medicine. Providers refusing to provide such information on the grounds of moral or religious objection fail in their fundamental duty to enable patients to make decisions for themselves. When the potential for imposition and breach of autonomy is high due either to controlling constraints on medication or procedures or to the provider's withholding of information critical to reproductive decision making, conscientious refusal cannot be justified.

2. Effect on Patient Health

A second important consideration in evaluating conscientious refusal is the impact such a refusal might have on well-being as the patient perceives it—in particular, the potential for harm. For the purpose of this discussion, harm refers to significant bodily harm, such as pain, disability, or death or a patient's conception of well-being. Those who choose the profession of medicine (like those who choose the profession of law or who are trustees) are bound by special *fiduciary duties*, which oblige physicians to act in good faith to protect patients' health—particularly to the extent that patients' health interests conflict with physicians' personal or self-interest (16). Although conscientious refusals stem in part from the commitment to "first, do no harm," their result can be just the opposite. For example, religiously based refusals to perform tubal sterilization at the time of cesarean delivery can place a woman in harm's way—either by putting her at risk for an undesired or unsafe pregnancy or by necessitating an additional, separate sterilization procedure with its attendant and additional risks.

Some experts have argued that in the context of pregnancy, a moral obligation to promote fetal well-being also should justifiably guide care. But even though views about the moral status of the fetus and the obligations that status confers differ widely, support of such moral pluralism does not justify an erosion of clinicians' basic obligations to protect the safety of women who are, primarily and unarguably, their patients. Indeed, in the vast majority of cases, the interests of the pregnant woman and fetus converge. For situations in which their interests diverge, the pregnant woman's autonomous decisions should be respected (18). Furthermore, in situations "in which maternal competence for medical decision making is impaired, health care providers should act in the best interests of the woman first and her fetus second" (19).

3. Scientific Integrity

The third criterion for evaluating authentic conscientious refusal is the scientific integrity of the facts supporting the objector's claim. Core to the practice of medicine is a commitment to science and evidence-based practice.

Patients rightly expect care guided by best evidence as well as information based on rigorous science. When conscientious refusals reflect a misunderstanding or mistrust of science, limits to conscientious refusal should be defined, in part, by the strength or weakness of the science on which refusals are based. In other words, claims of conscientious refusal should be considered invalid when the rationale for a refusal contradicts the body of scientific evidence.

The broad debate about refusals to dispense emergency contraception, for example, has been complicated by misinformation and a prevalent belief that emergency contraception acts primarily by preventing implantation (20). However, a large body of published evidence supports a different primary mechanism of action, namely the prevention of fertilization. A review of the literature indicates that Plan B can interfere with sperm migration and that preovulatory use of Plan B suppresses the luteinizing hormone surge, which prevents ovulation or leads to the release of ova that are resistant to fertilization. Studies do not support a major postfertilization mechanism of action (21). Although even a slight possibility of postfertilization events may be relevant to some women's decisions about whether to use contraception, provider refusals to dispense emergency contraception based on unsupported beliefs about its primary mechanism of action should not be justified.

In the context of the morally difficult and highly contentious debate about pregnancy termination, scientific integrity is one of several important considerations. For example, some have argued against providing access to abortion based on claims that induced abortion is associated with an increase in breast cancer risk; however, a 2003 U.S. National Cancer Institute panel concluded that there is well-established epidemiologic evidence that induced abortion and breast cancer are not associated (22). Refusals to provide abortion should not be justified on the basis of unsubstantiated health risks to women.

Scientific integrity is particularly important at the level of public policy, where unsound appeals to science may have masked an agenda based on religious beliefs. Delays in granting over-the-counter status for emergency contraception are one such example. Critics of the U.S. Food and Drug Administration's delay cited deep flaws in the science and evidence used to justify the delay, flaws these critics argued were indicative of unspoken and misplaced value judgments (23). Thus, the scientific integrity of a claim of refusal is an important metric in determining the acceptability of conscience-based practices or policies.

4. Potential for Discrimination

Finally, conscientious refusals should be evaluated on the basis of their potential for discrimination. Justice is a complex and important concept that requires medical professionals and policy makers to treat individuals fairly and to provide medical services in a nondiscriminatory manner. One conception of justice, sometimes referred to as the *distributive paradigm*, calls for fair allocation of society's benefits and burdens. Persons intending conscientious refusal should consider the degree to which they create or reinforce an unfair distribution of the benefits of reproductive technology. For instance, refusal to dispense contraception may place a disproportionate burden on disenfranchised women in resource-poor areas. Whereas a single, affluent professional might experience such a refusal as inconvenient and seek out another physician, a young mother of three depending on public transportation might find such a refusal to be an insurmountable barrier to medication because other options are not realistically available to her. She thus may experience loss of control of her reproductive fate and quality of life for herself and her children. Refusals that unduly burden the most vulnerable of society violate the core commitment to justice in the distribution of health resources.

Another conception of justice is concerned with matters of oppression as well as distribution (24). Thus, the impact of conscientious refusals on oppression of certain groups of people should guide limits for claims of conscience as well. Consider, for instance, refusals to provide infertility services to same-sex couples. It is likely that such couples would be able to obtain infertility services from another provider and would not have their health jeopardized, per se. Nevertheless, allowing physicians to discriminate on the basis of sexual orientation would constitute a deeper insult, namely reinforcing the scientifically unfounded idea that fitness to parent is based on sexual orientation, and, thus, reinforcing the oppressed status of same-sex couples. The concept of oppression raises the implications of all conscientious refusals for gender justice in general. Legitimizing refusals in reproductive contexts may reinforce the tendency to value women primarily with regard to their capacity for reproduction while ignoring their interests and rights as people more generally. As the place of conscience in reproductive medicine is considered, the impact of permissive policies toward conscientious refusals on the status of women must be considered seriously as well.

Some might say that it is not the job of a physician to "fix" social inequities. However, it is the responsibility, whenever possible, of physicians as advocates for patients' needs and rights not to create or reinforce racial or socioeconomic inequalities in society. Thus, refusals that create or reinforce such inequalities should raise significant caution.

Institutional and Organizational Responsibilities

Given these limits, individual practitioners may face difficult decisions about adherence to conscience in the context of professional responsibilities. Some have offered, however, that "accepting a collective obligation does not mean that all members of the profession are forced to violate their own consciences" (1). Rather, institutions and

professional organizations should work to create and maintain organizational structures that ensure nondiscriminatory access to all professional services and minimize the need for individual practitioners to act in opposition to their deeply held beliefs. This requires at the very least that systems be in place for counseling and referral, particularly in resource-poor areas where conscientious refusals have significant potential to limit patient choice, and that individuals and institutions "act affirmatively to protect patients from unexpected and disruptive denials of service" (13). Individuals and institutions should support staffing that does not place practitioners or facilities in situations in which the harms and thus conflicts from conscientious refusals are likely to arise. For example, those who feel it improper to prescribe emergency contraception should not staff sites, such as emergency rooms, in which such requests are likely to arise, and prompt disposition of emergency contraception is required and often integral to professional practice. Similarly, institutions that uphold doctrinal objections should not position themselves as primary providers of emergency care for victims of sexual assault; when such patients do present for care, they should be given prophylaxis. Institutions should work toward structures that reduce the impact on patients of professionals' refusals to provide standard reproductive services.

Recommendations

Respect for conscience is one of many values important to the ethical practice of reproductive medicine. Given this framework for analysis, the ACOG Committee on Ethics proposes the following recommendations, which it believes maximize respect for health care professionals' consciences without compromising the health and well-being of the women they serve.

1. In the provision of reproductive services, the patient's well-being must be paramount. Any conscientious refusal that conflicts with a patient's well-being should be accommodated only if the primary duty to the patient can be fulfilled.
2. Health care providers must impart accurate and unbiased information so that patients can make informed decisions about their health care. They must disclose scientifically accurate and professionally accepted characterizations of reproductive health services.
3. Where conscience implores physicians to deviate from standard practices, including abortion, sterilization, and provision of contraceptives, they must provide potential patients with accurate and prior notice of their personal moral commitments. In the process of providing prior notice, physicians should not use their professional authority to argue or advocate these positions.
4. Physicians and other health care professionals 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 their patients request.
5. In an emergency in which referral is not possible or might negatively affect a patient's physical or mental health, providers have an obligation to provide medically indicated and requested care regardless of the provider's personal moral objections.
6. In resource-poor areas, access to safe and legal reproductive services should be maintained. Conscientious refusals that undermine access should raise significant caution. Providers with moral or religious objections should either practice in proximity to individuals who do not share their views or ensure that referral processes are in place so that patients have access to the service that the physician does not wish to provide. Rights to withdraw from caring for an individual should not be a pretext for interfering with patients' rights to health care services.
7. Lawmakers should advance policies that balance protection of providers' consciences with the critical goal of ensuring timely, effective, evidence-based, and safe access to all women seeking reproductive services.

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XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
NELI N. PALMA, State Bar No. 203374
Deputy Attorney General
1300 I Street, Suite 125
Sacramento, CA 94244-2550
Telephone: (916) 210-7913
Fax: (916) 324-5567
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff the State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, BY AND THROUGH ATTORNEY GENERAL XAVIER BECERRA,

Plaintiff,

v.

ALEX M. AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,

Defendants,

4:19-cv-02769-HSG

DECLARATION OF MARI CANTWELL IN SUPPORT OF PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

I, Mari Cantwell, declare:

1. I am the Medicaid Director for the State of California and Chief Deputy Director of Health Care Programs at the California Department of Health Care Services (DHCS). I have held the Chief Deputy position since 2013 and the State Medicaid Director position since 2015. I have worked in the field of health care policy and finance for almost 20 years. Prior to the positions I hold now, I served as the Deputy Director of Health Care Financing for DHCS, and previously as the Vice President of Finance Policy for the California Association of Public

Hospitals and Health Systems. I hold a B.A. in Public Policy from Brown University, and a Masters in Public Policy with a focus in Health Policy from the University of California, Los Angeles.

2. DHCS has the mission to provide Californians with access to affordable, integrated, high-quality health care, including medical, dental, mental health, substance use treatment services, and long-term care. Our vision is to preserve and improve the overall health and well-being of all Californians. DHCS administers and oversees multiple federally-funded health care programs, including Medicaid, Children's Health Insurance Program, and several health-related federal grants. DHCS funds health care services for approximately 13 million members of Medi-Cal, California's Medicaid program. About one-third of Californians receive health care services through programs financed and administered by DHCS, making the department the largest health care purchaser in California. Among the programs administered by DHCS, some of which are mandated and/or financed by the federal government and others required by state law, are: Community Mental Health Block Grant; Substance Use Abuse Prevention and Treatment Block Grant; Medi-Cal Access Program; California Children's Services program; Child Health and Disability Prevention program; the Genetically Handicapped Persons Program; the Newborn Hearing Screening Program; the Family Planning, Access, Care, and Treatment program; Program of All-Inclusive Care for the Elderly, and Every Woman Counts. DHCS also administers programs for underserved Californians, including farm workers and American Indian communities.

3. I am familiar with the final rule entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" (the Rule), published in the Federal Register on May 21, 2019.

4. I anticipate that the Rule will increase costs for DHCS and all related sub-recipients, and will likely have negative impacts to health care access in the State.

5. The Rule will impose immediate costs on DHCS, which will be incurred across the fee-for-service and managed care Medi-Cal delivery systems and various other health care programs administered by DHCS. This includes, but is not necessarily limited to, the following

activities: changes to various DHCS webpages; preparation and physical posting of revised notices at all DHCS locations, including both for the public and for DHCS workforce; preparation and publication of revisions to DHCS applications, policy guidance and similar materials for providers, health plans, beneficiaries, other contractors or sub-recipients, and DHCS workforce; and providing notice to and overseeing implementation by all political subdivisions of the State, various DHCS contractors such as managed care plans, and various other sub-recipients of the implicated federal funds. As a preliminary estimate, DHCS projects immediate costs in the range of $3.5 Million to $4.5 Million (total funds). Such costs include projected staff and contractor expenses, as well as information technology/system costs over a variety of Medi-Cal delivery systems and other DHCS health care programs.

6. The Rule imposes significant ongoing recordkeeping and compliance costs on DHCS, particularly considering the many sub-recipients across various Medi-Cal delivery systems and separate DHCS-administered health care programs. Medi-Cal sub-recipients include independent political subdivisions of the State, such as counties. In order to comply with the Rule's assurance/certification and compliance processes, DHCS will need to develop and maintain a comprehensive system for tracking and monitoring compliance at DHCS, as well as compliance status of all sub-recipients to DHCS in the State. This system will require dedicated staff and contractor resources to fulfill the many compliance activities required in the Rule including, but not limited to: maintaining complete and accurate records of compliance with the Rule, including sub-recipients; tracking all accommodation requests and complaints across multiple programs; facilitating investigation of DHCS or any sub-recipient; implementing, or overseeing sub-recipient implementation of, any corrective action required under the Rule; and providing ongoing oversight of and training to the many sub-recipients across the State. As a preliminary estimate, DHCS projects annual recordkeeping and compliance costs in the range of $1 Million to $2 Million (total funds). Such costs include projected staff and contractor expenses, as well as information technology/system costs over a variety of Medi-Cal delivery systems and other DHCS health care programs.

7. The Rule places at risk all federal funds DHCS receives from the U.S. Department of Health and Human Services, as well as from the U.S. Department of Education and the U.S. Department of Labor. The approximated total amount of federal funds DHCS received in the 2018-19 State Fiscal Year was $63.68 Billion. Further, it is my understanding that a sub-recipient's violation of the Rule similarly places all federal funds at risk, in addition to DHCS compliance as a recipient.

8. The Rule will likely make it more difficult for beneficiaries of DHCS-administered programs to access an array of covered and medically appropriate services. Given the Rule's breadth, the potential for impeded access is not just with respect to a health care entity's ability to refuse to provide an affected service. Rather, that ability to abstain seemingly extends broadly and includes referrals and information sharing with a patient. Because of this, I believe it is likely the Rule will constrain provider supply and impede access to certain service categories, particularly in rural or otherwise underserved regions of the State. In addition, the potential for negative impacts would likely be disproportionately borne by vulnerable population groups, such as low-income women and the LGBTQ community. Further, these potential, negative impacts to access would be significantly exacerbated in the event a sizable portion of federal funds is withheld due to a violation by DHCS or one of its many sub-recipients.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct to the best of my knowledge.

Executed on May 23, 2019 in Sacramento, CA.

Mari Cantwell
Chief Deputy Director, Health Care Programs
California Department of Health Care Services

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, **v.** **ALEX M. AZAR, in his official capacity as Secretary of the U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; DOES 1-100,** Defendants.	4:19-cv-02769-HSG **[PROPOSED] ORDER GRANTING PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

Having considered the Plaintiff's motion for a preliminary injunction, IT IS HEREBY ORDERED that: The federal defendants are enjoined from enforcing the final rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 84 Fed. Reg. 23170 (May 21, 2019). Until resolution of this case, 76 Fed. Reg. 9968, 9971 (Feb. 23, 2011) shall remain in effect.

IT IS SO ORDERED.

Dated:

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HAYWOOD S. GILLIAM, JR.
United States District Judge