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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT YAKIMA

STATE OF WASHINGTON, Plaintiff, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; and UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	NO. 2:19-cv-00183-SAB STATE OF WASHINGTON'S MOTION FOR PRELIMINARY INJUNCTION NOTED FOR: July 17, 2019 With Oral Argument at 1:30 p.m.

TABLE OF CONTENTS

I. INTRODUCTION AND RELIEF REQUESTED 1

II. STATUTORY AND FACTUAL BACKGROUND 3

A. Federal Statutory and Regulatory Framework 3

1. Congress has enacted a statutory framework that mandates patient protections and patient access to health care 3

2. Congress has enacted appropriately limited refusal laws that protect conscience-based objections 4

B. Washington's Laws Respect Conscience Rights and Protect Patients 7

C. The HHS Rule 9

1. The Rule allows employees to assert a conscience objection to minor and administrative tasks incidentally connected to a medical procedure or service 9

2. The Rule broadens the entities and individuals who may claim a conscience objection 10

3. The Rule creates an absolute right to refuse to provide medical information or care 11

4. The Rule threatens state and local governments' unrelated funding streams for alleged non-compliance 13

D. Washington Agencies and Medical Institutions Provide Medical Care That Will Be Negatively Impacted By the Rule 14

III. ARGUMENT 17

A. Legal Standard 17

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

B. Washington Is Likely to Succeed on the Merits of Its Claims ... 18

1. Washington is likely to succeed on the merits of its claims under the Administrative Procedure Act (APA) 18

a. The Rule exceeds HHS's statutory authority 18

b. The Rule conflicts with existing healthcare laws..... 23

(1) The Rule is contrary to the ACA because it denies timely access to medical care, interferes with provider-patient communications, and undermines informed consent or medical ethics 24

(2) The Rule violates the ACA's anti-discrimination provisions 26

(3) The Rule violates the ACA's contraceptive coverage requirement..... 27

(4) The Rule violates EMTALA..... 28

(5) The Rule violates the non-directive pregnancy counseling mandate applicable to Title X of the Public Health Service Act..... 29

c. The Rule is arbitrary and capricious 31

(1) The Rule's expansion of the scope of covered conduct makes the Rule arbitrary and capricious . 31

(2) HHS's analysis of the costs and benefits of the Rule is counter to the evidence before the agency 33

(3) The assurance and certification requirements are arbitrary and capricious..... 37

2. Washington is likely to succeed on the merits of its separation of powers argument..... 38

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

3. Washington is likely to succeed on the merits of its spending clause argument 40

a. The Rule is coercive 40

b. The Rule is vague and ambiguous 42

c. The Rule lacks a nexus to the federal funds it threatens 43

4. Washington is likely to succeed on the merits of its establishment clause argument 43

a. The Rule impermissibly burdens patients and third parties with employees' religious beliefs 44

b. The Rule impermissibly coerces patients and providers to adhere to government favored religious practices 45

C. Washington Will Suffer Irreparable Harm Absent Preliminary Relief 46

1. The Rule will harm Washingtonians 46

2. The missions of Washington's agencies and medical institutions will be harmed and compromised 48

3. Washington will be preempted from enforcing its longstanding laws safeguarding patient care 49

4. Washington will incur substantial and uncompensable costs 51

5. The Rule threatens loss of over $10 billion in funding 52

6. Constitutional violations are irreparable harms 53

D. Equity and the Public Interest Strongly Favor an Injunction 53

E. Relief Requested 54

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
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Seattle, WA 98104-3188
(206) 464-7744

IV. CONCLUSION 54

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
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TABLE OF AUTHORITIES

Cases

ACA Int'l v. F.C.C.,
885 F.3d 687 (D.C. Cir. 2018) 22, 32

Bauer v. DeVos,
325 F. Supp. 3d 74 (D.D.C. 2018) 54

Burwell v. Hobby Lobby Stores, Inc.,
134 S. Ct. 2751 (2014) 44

California v. Azar,
2019 WL 1877392, *rev'd on other grounds* __ F.3d __, 2019 WL 2529259 (9th Cir. 2019) 36

California v. Azar,
911 F.3d 558 (9th Cir. 2018).....3, 46, 49

California v. Health & Human Servs.,
281 F. Supp. 3d 806 (N.D. Cal. 2017) 46

Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.,
467 U.S. 837 (1984) 23

City & County of San Francisco v. Sessions,
372 F. Supp. 3d 928 (N.D. Cal. 2019) 39

City of Arlington v. F.C.C.,
569 U.S. 290 (2013) 18, 38

City of Kansas Cit., Mo. v. Dep't of Housing & Urban Dev.,
923 F.2d 188 (D.C. Cir. 1991) 37

City of Los Angeles v. Sessions,
293 F. Supp. 3d 1087 (C.D. Cal. 2018) 35, 54

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

City of Philadelphia v. Attorney Gen. of the United States,
916 F.3d 276 (3d Cir. 2019) 18

Clinton v. City of New York,
524 U.S. 417 (1998) 38

CSX Transp., Inc. v. Ala. Dep't of Revenue,
562 U.S. 277 (2011) 22

Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.,
538 F.3d 1172 (9th Cir. 2008) 35

Cutter v. Wilkinson,
544 U.S. 709 (2005) 44

Diaz v. Brewer,
656 F.3d 1008 (9th Cir. 2011) 53

Drakes Bay Oyster Co. v. Jewell,
747 F.3d 1073 (9th Cir. 2014) 53

Eberhardt v. City of Los Angeles,
62 F.3d 1253 (9th Cir. 1995) 28

Estate of Thornton v. Caldor, Inc.,
472 U.S. 703 (1985) 23, 44, 45

F.C.C. v. Fox Television Stations, Inc.,
556 U.S. 502 (2009) 18, 38

Fed. Election Comm'n v. Democratic Senatorial Campaign Comm.,
454 U.S. 27 (1981) 23

Fin. Planning Ass'n v. Sec. & Exch. Comm'n,
482 F.3d 481 (D.C. Cir. 2017) 20

Gebser v. Lago Vista Ind. Sch. Dist.,
524 U.S. 274 (1998) 41

Gonzales v. Oregon,
546 U.S. 243 (2006) 18, 19

Hernandez v. Sessions,
872 F.3d 976 (9th Cir. 2017) 17

In re Aiken County,
725 F.3d 255 (D.C. Cir. 2013) 38, 39

Kern v. U.S. Bureau of Land Mgmt.,
284 F.3d 1062 (9th Cir. 2002) 35

King v. Burwell,
135 S. Ct. 2480 (2015) 23

Larson v. Valente,
456 U.S. 228 (1982) 44

League of Women Voters of the U.S. v. Newby,
838 F.3d 1 (D.C. Cir. 2016) 33, 48, 53

Lee v. Weisman,
505 U.S. 577 (1992) 45

McCreary County v. ACLU of Ky.,
545 U.S. 844 (2005) 43

Melendres v. Arpaio,
695 F.3d 990 (9th Cir. 2012) 53

Michigan v. E.P.A.,
135 S. Ct. 2699 (2015) 34, 37

Mingo Logan Coal Co. v. E.P.A.,
829 F.3d 710, (D.C. Cir. 2016) 36

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983) 31, 34

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
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Nat'l Ass'n of Home Builders v. E.P.A.,
682 F.3d 1032 (D.C. Cir. 2012) 34

Nat'l Fed'n of Indep. Bus. v. Sebelius (*NFIB*),
567 U.S. 519 (2012) 40, 41

Nat'l Fuel Gas Supply Corp.,
468 F.3d 831 (D.C. Cir. 2006) 36

New England Coal. on Nuclear Pollution v. Nuclear Regulatory Comm'n,
727 F.2d 1127 (D.C. Cir. 1984) 35

New York v. United States,
505 U.S. 144 (1992) 43

Nw. Envtl. Advocates v. E.P.A.,
537 F.3d 1006 (9th Cir. 2008).....23

Oona v. Santa Rosa Cty. Schs.,
890 F. Supp. 1452 (N.D. Cal. 1995) 41

Pennsylvania v. Trump,
351 F. Supp. 3d 791 (E.D. Pa. 2019) 46

R.F.M. v. Nielsen,
365 F. Supp. 3d 350 (S.D.N.Y. 2019).....38

Regents of the Univ. of Cal. v. U.S. Dep't of Homeland Sec.,
908 F.3d 476 (9th Cir. 2018).....54

Santa Fe Indep. Sch. Dist. v. Doe,
530 U.S. 290 (2000) 43

Saravia for A.H. v. Sessions,
905 F.3d 1137 (9th Cir. 2018).....17

South Dakota v. Dole,
483 U.S. 203 (1987) 40, 42, 43

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Texas Monthly, Inc. v. Bullock,
489 U.S. 1 (1989) 44

Valle del Sol Inc. v. Whiting,
732 F.3d 1006 (9th Cir. 2013) 48

Washington v. Azar,
__ F. Supp. 3d __, 2019 WL 1868362 (9th Cir. 2019) 24, 29

Water Quality Ins. Syndicate v. United States,
225 F. Supp. 3d 41 (D.D.C. 2016) 33

Zubik v. Burwell,
136 S. Ct. 1557 (2016) 27

Statutes

5 U.S.C. § 705 54

5 U.S.C. § 706 18

5 U.S.C. § 706(2) 31

5 U.S.C. § 706(2)(A) 23

5 U.S.C. § 706(2)(C) 18, 23

42 U.S.C. § 238n(c)(2) 6, 10, 19, 39

42 U.S.C. § 1395dd 4, 23

42 U.S.C. § 1395dd(b)(1) 4

42 U.S.C. § 1395dd(d) 4

42 U.S.C. § 1395dd(e)(1) 4, 28

42 U.S.C. § 18023(d) 4

42 U.S.C. § 18113……..39
42 U.S.C. § 18113(b)……..19
42 U.S.C. § 18114……3
42 U.S.C. § 18114(1)……..24
42 U.S.C. § 18114(2)……..24
42 U.S.C. § 18114(3)……..24
42 U.S.C. § 18114(4)……..24
42 U.S.C. § 18116……..3, 23
42 U.S.C. § 18116(a)……..26
42 U.S.C. § 2000e(j)……4
42 U.S.C. § 2000e-2(a)……...4, 12
42 U.S.C. § 2000e-2(j)……...12
42 U.S.C. § 238n(a)(1)……6
42 U.S.C. § 238n(a)(2)……6
42 U.S.C. § 238n(b)(1)……....6
42 U.S.C. § 238n(b)(2)(A)……...6
42 U.S.C. § 300a-7(c)……...21, 38
42 U.S.C. § 300a-7(c)(1)……..6
42 U.S.C. § 300a-7(c)(2)……..6
42 U.S.C. § 300a-7(d)……...7

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

42 U.S.C. § 300a-7(e)……...6

42 U.S.C. § 300gg-13(a)(4)……3, 27

2019 Wash. Sess. Laws, ch. 399, § 1(3)……50

2019 Wash. Sess. Laws, ch. 399, § 2(1)……...8

Pub. L. No. 115-245, 132 Stat. 2981 (Sept. 28, 2018)……passim

Wash. Rev. Code 7.7.050 8

Wash. Rev. Code 9.02.100, *et seq*……8

Wash. Rev. Code 9.02.100(4).....50

Wash. Rev. Code 9.02.110 50

Wash. Rev. Code 48.43.065(2)(a) 7, 8

Wash. Rev. Code 48.43.065(2)(b).....8

Wash. Rev. Code 48.43.072……8

Wash. Rev. Code 48.43.073……8

Wash. Rev. Code 70.41.350……...8, 49

Wash. Rev. Code 70.47.160(2)(a) 8

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Wash. Rev. Code 70.122.060(2).....8, 50

Wash. Rev. Code 70.170.060 50

Wash. Rev. Code 70.245.190(d).....8, 50

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
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Regulations

73 Fed. Reg. 78072 (Dec. 19, 2008).....26, 35

76 Fed. Reg. 9968 (Feb. 23 2011).....38

83 Fed. Reg. 3880 (Jan. 26, 2018).....38

84 Fed. Reg. 23170 (May 21, 2019).....passim

84 Fed. Reg. 26580 (June 7, 2019).....9

Wash. Admin. Code 246-869-010.....8, 50

Other Authorities

119 Cong. Rec. 9597 (Mar. 27, 1973).....21

American Academy of Pediatrics & The American College of Obstetricians & Gynecologists, Guidelines for Perinatal Care, p. 127 (7th ed. 2016) 30

Black's Law Dictionary 534 (9th ed. 2009).....22

ATTORNEY GENERAL OF WASHINGTON
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I. INTRODUCTION AND RELIEF REQUESTED

On May 21, 2019, the U.S. Department of Health and Human Services (HHS) issued a final rule, *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23170 (Rule), interpreting nearly thirty federal statutes to dramatically expand what it calls "conscience rights in healthcare." The "rights" HHS purports to recognize authorize medical providers and institutions to violate other federal statutes protecting patients. And if Washington fails to comply, it risks losing over $10 billion in funding from programs authorized by Congress—programs like Medicaid and children's health insurance essential to low-income Washington families—even if the programs are completely unrelated to those in which any alleged conscience violations occur. Worse, the Rule makes Washington's continued receipt of federal health care funds contingent not only on *its* compliance with the Rule, but also with the compliance of any contractor or subgrantee it uses to implement joint federal-state health care programs.

The Rule is a continued chapter in HHS's efforts to stamp certain religious views onto how healthcare is provided in the United States. In its fervency to enforce these views on all Americans, however, it continues to ignore Congressional directives that limit its authority. HHS assumes that it can empower providers and institutions to disregard duly enacted federal laws such as the Patient Protection and Affordable Care Act (ACA), the Emergency

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Seattle, WA 98104-3188
(206) 464-7744

Medical Treatment and Labor Act, the Nondirective Mandate applicable to Title X of the Public Health Service Act, and Title VII of the Civil Rights Act of 1964. In violation of these statutes, the Rule impedes access to health care information or services, violates principles of informed consent, and undercuts the ethical standards of health care professionals. Although HHS hopes to capitalize on the broad deference sometimes accorded by courts to agency action, HHS does not have authority to disregard or overrule statutory commands.

Washington moves for a preliminary injunction prohibiting HHS from implementing the Rule, which is scheduled to go into effect on July 22, 2019. Washington has a carefully constructed tapestry of laws that balance providers' conscience rights with patients' rights to modern healthcare. HHS's Rule preempts all these laws. If allowed to go into effect on July 22, 2019, the Rule will have destabilizing impacts on Washington and its citizens. It will result in patients receiving incomplete, biased, dishonest, and medically-inaccurate care because patients will be denied counseling on a complete range of options and advice potentially without their knowledge—a harm that doctors believe will be an affront to their oaths. It will invalidate the State's informed consent law. It will require the State's medical institutions to change their staffing practices in their emergency rooms and to change their policies prohibiting discrimination against gay, lesbian, and transgender individuals. It will cause agencies to cut services or funding. And it puts at risk all federal funding from HHS. And that does not even

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(206) 464-7744

account for the downstream public health consequences of these impacts. To prevent harm to patients, doctors, and the agencies tasked with providing or overseeing medical care, the Court should preliminarily enjoin the Rule.

II. STATUTORY AND FACTUAL BACKGROUND

A. Federal Statutory and Regulatory Framework

1. Congress has enacted a statutory framework that mandates patient protections and patient access to health care

Congress has enacted into law affirmative requirements, disregarded by HHS in the Rule, to ensure Americans' access to modern and effective health care. These include the Patient Protection and Affordable Care Act (ACA), Title VII of the Civil Rights Act of 1964, and the Emergency Medical Treatment and Labor Act (EMTALA). The ACA mandates that HHS cannot promulgate any regulation that impedes the timely access to health care, creates unreasonable barriers to receiving care, restricts the ability of providers to provide healthcare information to patients, or interferes with principles of informed consent. 42 U.S.C. § 18114. The ACA also prohibits discrimination in the provision of healthcare services. 42 U.S.C. § 18116. And it requires insurers to provide contraceptive coverage. 42 U.S.C. § 300gg-13(a)(4); *California v. Azar*, 911 F.3d 558, 566 (9th Cir. 2018).[1]

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[1]And with respect to appropriations for family planning services since 1996, Congress has made clear that all pregnancy counseling shall be non-

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(206) 464-7744

Title VII of the Civil Rights Act of 1964 requires accommodations of religious beliefs only when they do not impose undue hardship on the employer's operations. 42 U.S.C. §§ 2000e-2(a), 2000e(j). This ensures that employers, like medical providers, can hire and utilize employees who will provide the services employers intend to provide.

In 1986, Congress enacted the EMTALA to ensure public access to emergency services regardless of a patient's ability to pay. 42 U.S.C. § 1395dd. Hospitals must provide patients with a medical screening examination, and either treat or transfer patients with an emergency medical condition, defined as a condition of such severity that the absence of immediate medical attention could reasonably result in placing the health of the patient in serious jeopardy. 42 U.S.C. §§ 1395dd(b)(1), 1395dd(e)(1); 42 U.S.C. § 18023(d) (healthcare providers must "provid[e] emergency services as required by State or Federal law"). A hospital's failure to comply with EMTALA is subject to civil penalties and the threat of Medicare decertification. 42 U.S.C. § 1395dd(d).

2. Congress has enacted appropriately limited refusal laws that protect conscience-based objections

Relevant here, Congress has enacted three appropriately limited statutes that prohibit discrimination against individuals and entities that exercise a

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directive. Department of Health and Human Services Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981 (Sept. 28, 2018).

religious or moral objection to providing specific information, referrals, or services. Notably, these statutes do not give HHS authority to place conditions on federal grants or withhold federal grants authorized by Congress

First, the Weldon Amendment covers persons and entities who do not wish to participate in abortion care, providing that no funds appropriated under a particular appropriations statute "may be made available to a Federal agency or program, or to a State or local government," if the recipient "subjects any institutional or individual healthcare entity to discrimination on the basis that the healthcare entity does not provide, pay for, provide coverage of, or refer for abortions." Pub. L. No. 115-245, § 507(d)(1), 132 Stat. 2981, 3118 (Sept. 28, 2018). The Weldon Amendment's application is expressly limited to health care entities which it defines as "an individual physician or health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." *Id.* § 507(d)(2).

Second, the Coats-Snowe Amendment is focused specifically on training to provide abortion. It prohibits federal, state, and local governments that receive federal funding from discriminating against a health care entity on the basis that the entity refuses to perform abortions, to receive, require, or provide training in abortion services, to provide referrals for training or performance of abortion services, or to refuse to make arrangements for abortions. 42 U.S.C. §

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238n(a)(1)–(2). It also requires federal, state, and local governments to grant accreditation to any health care entity, including internship and residency programs, that would otherwise receive accreditation but for accreditation standards that require performance of or training in abortion services. *Id.* § 238n(b)(1)–(2)(A). Like the Weldon Amendment, the Coats-Snowe Amendment limits its application to health care entities, which include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." *Id.* § 238n(c)(2).

Third, the Church Amendments' focus is on biomedical research. Among other things, they prohibit recipients of "biomedical or behavioral research" funds from discriminating against personnel because they performed or assisted in the performance of a research or health care activity, or refused to do so because of religious beliefs or moral convictions. 42 U.S.C. § 300a-7(c)(2). They also prohibit recipients of certain federal funds from discriminating in employment against physicians or health care personnel because they "performed or assisted in the performance of a lawful sterilization procedure or abortion" or refused to do so, *id.* § 300a-7(c)(1), and they prohibit recipients of certain federal funds from discriminating against applicants for training or study based on their "reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations." *Id.* § 300a-7(e). Finally, they provide that "[n]o individual shall be required to perform or assist

in the performance of any part of a health service program or research activity funded . . . under a program administered by [HHS]" if the activity "would be contrary to his religious beliefs or moral convictions." *Id.* § 300a-7(d).[2]

These carefully drafted statutes focus on specific issues and none extend an all-purpose right to object to all employees of healthcare providers. And none suggest religious objections may take priority over patient care. None extend an all-purpose religious-objection right to every person employed by a healthcare provider. Congress has never suggested that religious objections take priority over patients' needs or the healthcare system.

B. Washington's Laws Respect Conscience Rights and Protect Patients

Washington's legislature has crafted a careful balance between individuals' religious and moral beliefs and patients' rights. Specifically, Washington's conscience protection statute provides that:

> No individual health care provider, religiously sponsored health carrier, or health care facility may be required by law or contract in any circumstances to participate in the provision of or payment for a specific service if they object to so doing for reason of conscience or religion.

Wash. Rev. Code 48.43.065(2)(a). Nor are individuals or organizations with a religious or moral tenet "required to purchase [insurance] coverage for that

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[2] While other federal laws containing conscience right provisions exist, these Amendments are most relevant to HHS's claimed statutory authority for the provisions at issue.

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service or services if they object to doing so for reason of conscience or religion." Wash. Rev. Code 48.43.065(2)(b); *see also* Wash. Rev. Code 70.47.160(2)(b). The statute also protects persons from discrimination "in employment or professional privileges" because they assert a conscience objection. Wash. Rev. Code 48.43.065(2)(a); *see also* Wash. Rev. Code 70.47.160(2)(a).

As a counterbalance, Washington public policy and health care statutes respect the rights of Washington residents to receive appropriate and fully informed medical care consistent with federal law, state law, and longstanding medical standards and ethical rules. These laws include the Reproductive Privacy Act, Wash. Rev. Code 9.02.100, *et seq*.; the Reproductive Parity Act, Wash. Rev. Code 48.43.072–.073; Washington's Informed Consent statute, Wash. Rev. Code 7.7.050; Washington's regulation governing pharmacies' responsibilities, Wash. Admin. Code 246-869-010; its statute mandating emergency contraception for sexual assault victims, Wash. Rev. Code 70.41.350; the duty to counsel on advanced directives, Wash. Rev. Code 70.122.060(2); the duty to transfer medical records of patients seeking end-of-life care, Wash. Rev. Code 70.245.190(d); the statute prohibiting health care-related discrimination based on gender identity, 2019 Wash. Sess. Laws, ch. 399, § 2(1); and Washington's charity care law prohibiting patient abandonment, among other laws. *See* Complaint ¶¶ 16–32.

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C. The HHS Rule

On May 21, 2019, HHS published the Rule with an effective date of July 22, 2019. 84 Fed. Reg. at 23170 (attached hereto as Exhibit 1); *see* 84 Fed. Reg. 26580 (June 7, 2019) (corrected publication date). The Rule's purpose is to "protect the rights of individuals, entities, and health care entities to refuse to perform, assist in the performance of, or undergo health care services or research activities to which they may object for religious, moral, ethical, or other reasons." 84 Fed. Reg. at 23263.

1. The Rule allows employees to assert a conscience objection to minor and administrative tasks incidentally connected to a medical procedure or service

The Rule grants individuals a right to refuse to disclose ethically-required information about appropriate and medically-indicated services that goes far beyond what the statutes themselves provide. *See* 84 Fed. Reg. at 23263. The Rule's broad definition of "assist in the performance" includes any actions that may provide "aid" in "furthering" a procedure—including *any* "provision of information" where an objected-to service is a "reasonably foreseeable outcome." 84 Fed. Reg. at 23263–64. A conscience objector can refuse to "provide information" in "oral, written, or electronic form." *Id.* at 23264. Under this expansive definition, a conscience objector would not have to provide contact information of a physician or clinic that may provide an abortion, tell a patient that funding is available for abortion, or provide a phone number where she can

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Seattle, WA 98104-3188
(206) 464-7744

be referred to abortion services or funding. *Id.* at 23188. Even the posting of notices is considered a "referral." *Id.* The Rule appears to permit employees to refuse to provide information on all options, even when requested by a patient. *Id.* at 23188 ("Counseling and referral are common and well understood forms of assistance that materially help people reach desired medical ends"). HHS also explicitly refused to respond to a comment expressing concern that "the definition of 'assist in the performance' will result in conscientious objectors refusing to provide information to patients about objected-to treatment options, potentially in violation of informed consent" and instead dodged the question by responding "This rule will not change the obligation that, absent exigent circumstances, doctors secure informed consent before engaging in a medical procedure." *Id*. at 23189.

2. The Rule broadens the entities and individuals who may claim a conscience objection

The Rule vastly increases the universe of employees who may now conscientiously object. *See* 84 Fed. Reg. at 23263–64 (§ 88.2). The new definition of "health care entity" expands the applicable statutes to include, among other categories, all "health care personnel . . . or any other health care provider or health care facility." *Id.* at 23264. This definition is far broader than the specific definitions of "health care entity" contained in the Coats-Snowe Amendment, *see* 42 U.S.C. § 238n(c)(2) ("an individual physician, a postgraduate physician training program, and a participant in a program of

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training in the health professions"), or the Weldon Amendment, *see* Pub. L. No. 115-245, § 507(d)(2), ("an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan").

In addition to the "health care personnel" reasonably understood to "assist in the performance" of a medical procedure, the Rule extends conscience protections to anyone who "otherwise mak[es] arrangements for [an objected-to] procedure . . ."—a sweeping definition that explicitly includes ambulatory Emergency Medical Technicians (EMTs) and paramedics, 84 Fed. Reg. at 23188, as well as front desk receptionists, clerks who input insurance information, and drivers who transport a patient from one place to another. *Id.* at 23263.

3. The Rule creates an absolute right to refuse to provide medical information or care

Under the Rule, the State and its sub-recipients cannot ask prospective employees whether they are willing to perform the essential functions of the job they are seeking, even if, as a result, the State or its sub-recipients hire an employee that is unable to deliver health care services critical to the entity's mission. HHS explicitly declined to state that health care employers subject to the Rule are permitted to reject job candidates who refuse to perform or assist in the performance of a health service that comprises "the primary or substantial majority of the duties of the position." *Id.* at 23192. Once hired, the Rule prohibits

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asking employees if they object to the performance of any of their job functions more than once per calendar year absent an undefined "persuasive justification." *Id.* at 23263. Consequently, a conscience objector has no obligation to let their employer or patient know when they are withholding information or services.

Finally, the State and its sub-recipients must provide *absolute* accommodation to individuals who refuse to provide certain information and services to their patients, even in emergencies, or when providing such information and services is one of the primary duties of the job. *Id.* at 23190–91. By expressly providing that it does not incorporate an assessment of undue hardship or other burden on employers, the Rule abandons Title VII's long-standing balancing framework applied to religious accommodations in healthcare. 42 U.S.C. §§ 2000e-2(a), 2000e-2(j). Thus an employer can offer an accommodation to an employee who can refuse to accept regardless of the reasonableness of the accommodation. 84 Fed. Reg. at 23191. The employer cannot use alternate staff to provide objected-to medical services if doing so would require the conscience objector to take "any" additional action (such as informing other non-objecting staff), or if it would functionally exclude the objector from any "fields of practice." *Id.* Indeed, should a health care employer seek to inform their patients of their right to receive full information about all of their options by posting a notice to patients informing them that there is a staff

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member who refuses to provide certain care, the OCR could deem it "discrimination" against the objecting employee. *Id.* at 23263.

4. The Rule threatens state and local governments' unrelated funding streams for alleged non-compliance

The Rule authorizes HHS to withhold, deny, suspend, claw back, or terminate "Federal financial assistance or other Federal funds" if it determines that there is a "failure to comply." *Id.* at 23271–72. The Rule does not appear to require any nexus between the funding subject to termination and the alleged violation, placing at risk not only the State's receipt of all federal funds from HHS, but also federal funds from the Department of Labor and Department of Education that are implicated by the Weldon Amendment, including, potentially, funds entirely unrelated to health care. *See id.* at 23172 (Weldon implicates "funds made available in the applicable Labor, HHS, and Education appropriations act"); *id.* (a finding of violation "threaten[s]" all funding streams implicated by any of the statutes that the Rule purports to implement; *id*. at 23223; *id.* at 23265–66, 23272. The Rule authorizes HHS to initiate compliance reviews based on information from a complaint "or other source"—even if the basis of the complaint is not actual noncompliance, but merely a "threatened" or "potential" failure to comply.

In another departure from the previous rule, the Rule "clarifies" that States are "responsible for their own compliance with Federal conscience and anti-discrimination laws and implementing regulations, as well as for ensuring their

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sub-recipients comply with these laws." *Id.* at 23180. Actual or threatened non-compliance by any of the State's sub-recipients could lead the HHS to withhold, deny, suspend, or terminate billions of dollars in federal funds. *Id.* at 23271–72 (§ 88.7(i)).

D. Washington Agencies and Medical Institutions Provide Medical Care That Will Be Negatively Impacted By the Rule

Washington has numerous agencies and medical institutions that provide medical care to Washingtonians that will be negatively impacted by the Rule. Washington State is home to many vulnerable populations with limited access to medical care. This can be because the individual lives in a rural area where more travel is required and fewer providers are available, because of socio-economic status, or because of fear of discrimination when seeking medical care. Declaration of Cynthia Harris in Support of State of Washington's Motion for Preliminary Injunction (Harris Decl.) ¶¶ 17–18, 21; Declaration of Bill Moss in Support of State of Washington's Motion for Preliminary Injunction (Moss Decl.) ¶ 34. In these situations, the refusal to dispense pharmaceuticals, give accurate advice, or refer to another provider can be "more than just a slight inconvenience for people—it is depriving them of critical, lifesaving services and supports needed to maintain their health and well-being." Moss Decl. ¶ 21; *see also* Declaration of Christopher M. Zahn, MD in Support of State of Washington's Motion for Preliminary Injunction (Zahn Decl.) ¶ 8; Declaration of Mike Kreidler in Support of State of Washington's Motion for Preliminary

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Injunction (Kreidler Decl.) ¶ 6. And even in those situations where a provider will choose to refer, it can be difficult to find someone else to treat in a timely manner and the referrals can place greater strain on already busy providers or result in disruption to patient care. Declaration of Maureen Broom in Support of State of Washington's Motion for Preliminary Injunction (Broom Decl.) ¶¶ 14, 17; Declaration of Mary Jo Curry in Support of State of Washington's Motion for Preliminary Injunction (Currey Decl.) ¶¶ 17–19; Declaration of Ellen B. Taylor, Ph.D in Support of State of Washington's Motion for Preliminary Injunction (Taylor Decl.) ¶ 12. Worse, if the Rule is successful in eliminating barriers to the healthcare field for conscience objectors, this strain on non-objectors and the concomitant disruption to patient care will grow exponentially with time.

As a representative sample, the following agencies and State institutions have identified harms to them and their clients because of the Rule:

- Washington State University's (WSU's) $100 million in federal funds from HHS for its medical facilities and student health care, among other things, will be put at risk. Taylor Decl. ¶ 6. Located in a rural area, its student health service (Cougar Health), which serves a large LGTBQ population and provides services for students' reproductive health, will be particularly affected if staff exercise conscience objections and delay or deny care. *Id.* ¶¶ 10–12. WSU estimates it would cost at least $500,000 to implement the Rule. *Id.* ¶¶ 13–15.

- University of Washington (UW) receives over $1.167 billion in federal funds from HHS for its medical facilities and student health care, which will be put at risk by the Rule. Broom Decl. ¶ 5. As a health care entity providing unique health care services in emergency situations, UW Medicine could be particularly affected by conscience objections if a staff

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member's conscience objections cause the delay or denial of care. *Id.* ¶¶ 16–21. UW estimates it would cost $8.2 million to create the systems necessary to implement the Rule, with $1 million to $3 million in ongoing costs. *Id.* ¶¶ 9, 14.

- The Office of Insurance Commissioner (OIC), which is tasked with enforcing the ACA and regulating health insurance companies in Washington, explains that the Rule will cause serious harm to rural communities, members of the LGTBQ community, and women seeking reproductive care. Kreidler Decl.

- Because the Rule conflicts with State laws requiring reproductive parity, Washington's Department of Health (DOH) will likely have to withdraw from the federal Title X program, which accounts for about $4 million in federal funds. Harris Decl. ¶¶ 51–53, 60. This will cause long-term health consequences to women and families. *Id.* ¶¶ 54–61.

- The Health Care Authority (HCA), as the largest health care purchaser in Washington, will risk losing its $8.4 billion in federal funds from HHS. Lindeblad Decl. ¶¶ 3–4. The Rule's breadth will decrease access to critical services in rural or otherwise underserved areas and will have negative impacts disproportionately borne by low-income women and the LGBTQ community. *Id.* ¶ 13.

- The Department of Corrections (DOC) operates twelve prisons and twelve work release facilities and is responsible for providing housing, food, and health care to over 19,361 inmates, with a staff of over 940 health care professionals and support personnel that provide health services. Currey Decl. ¶¶ 8–9. Providing health care for incarcerated individuals poses unique challenges to the point that if even one provider is allowed to refuse to provide medically necessary care. *Id.* ¶ 11. The Rule may cause DOC to fail in its obligation to provide medically necessary medical and mental health care under the Eight and Fourteenth Amendments, potentially causing significant tort liability. *Id.* ¶ 10.

- The Department of Social and Health Services (DSHS) estimates the Rule puts its approximately $2.5 billion in federal funding at risk. Moss Decl. ¶¶ 3, 23. DSHS anticipates the Rule will negatively impact the citizens it serves particularly in rural regions that lack a variety of providers by creating increased health disparities between communities and depriving people of critical care. *Id.* ¶¶ 18–21. Additionally DSHS has thousands of sub-recipients which assist in providing care to over 100,000 individuals. ¶¶ 24–25 and 48. DSHS estimates that, to implement the Rule in the next

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twelve months, the cost is $14,574,000 for its aging and long term support program and its developmental disabilities administration alone. *Id*. ¶ 42.

- The Washington State Pharmacy Quality Assurance Commission's (PQAC's) rules allow an individual pharmacist to exercise their religious or moral objections, but require the pharmacy to still ensure all lawfully prescribed drugs or devices are delivered by having another pharmacist available in person or by telephone. Declaration of Steven Saxe in Support of State of Washington's Motion for Preliminary Injunction (Saxe Decl.) ¶¶ 7–11. PQAC believes that the Rule will require it to repeal its pharmacy rules, *id*. ¶ 15, thereby allowing pharmacies to refuse to fill prescriptions based on a religious or conscience objections, harming the health, safety, and welfare of Washington citizens. *Id*. ¶ 14.

III. ARGUMENT

A. Legal Standard

"The familiar *Winter* standard provides that 'a plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.' " *Saravia for A.H. v. Sessions*, 905 F.3d 1137, 1142 (9th Cir. 2018) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). Under the Ninth Circuit's "sliding scale" approach, these elements are "balanced, so that a stronger showing of one element may offset a weaker showing of another." *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017).

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B. Washington Is Likely to Succeed on the Merits of Its Claims

1. Washington is likely to succeed on the merits of its claims under the Administrative Procedure Act (APA)

The Rule should be "[held] unlawful and set aside" because it exceeds the agency's rulemaking authority, is contrary to the law HHS purports to interpret as well as multiple controlling statutes, and is arbitrary and capricious. 5 U.S.C. § 706.

a. The Rule exceeds HHS's statutory authority

The Rule violates the APA because it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). In determining whether agency action exceeds statutory authority, "the question is always whether the agency has gone beyond what Congress has permitted it to do." *City of Arlington v. F.C.C.*, 569 U.S. 290, 29–98 (2013). Here, the Rule has impermissibly expanded the reach of congressional enactments by redefining key terms far beyond what Congress has permitted: "health care entity," "assist in the performance of," and "discrimination or discriminate."

"Health care entity." Three statutes that the Rule implements (the Coats-Snowe Amendment, the Weldon Amendment, and Section 1553 of the ACA) expressly define the term "health care entity." The Rule exceeds HHS's authority by expanding the statutes to include entirely different individuals and entities not identified by Congress. *See F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 541 (2009) (agencies are "constrained by [their] congressional

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mandate"); *Gonzales v. Oregon*, 546 U.S. 243, 269–73 (2006); *City of Philadelphia v. Attorney Gen. of the United States*, 916 F.3d 276, 284–91 (3d Cir. 2019).

The Coats-Snowe Amendment defines "health care entity" as "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n(c)(2). But the Rule broadens Coats-Snowe's application from a narrow class focusing on physicians and those training in the health profession to an expansive regulatory definition including the entire health sector, any pharmacies, entities engaging in behavioral research, any "health care professional," and their "health care personnel." *Id.*

The Weldon Amendment similarly defines the term "health care entity" to include "an individual physician or health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization or plan." Pub. L. No. 115-245, § 507(d)(2). Section 1553 of the ACA uses this same definition. 42 U.S.C. § 18113(b). The Rule again extends this definition to include (in addition to the overbroad categories described above) entities that are entirely outside the health profession, like health plan sponsors (typically employers), plan issuers (such as insurance companies), and third-party administrators (that perform claims processing and administrative tasks). *See* 84

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Fed. Reg. at 23264. Congress could not have intended the statute's text include entire classes of entities distinct from those listed in the statute. *Gonzales*, 546 U.S. at 269–73.

"Assist in the performance." The Rule defines the term "assist in the performance" to mean "to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity," which "may include counseling, referral, training, . . . or otherwise make arrangements for the procedure . . . , depending on whether aid is provided by such actions." 84 Fed. Reg. at 23263 (§ 88.2). While this claims to implement the Church Amendment, the context, structure, and legislative history make clear that the Rule has expanded the meaning of the term beyond what Congress provided. *See Fin. Planning Ass'n v. Sec. & Exch. Comm'n*, 482 F.3d 481, 487 (D.C. Cir. 2017).

Specifically, while Congress used the term "counseling" in other Church Amendment provisions, "training" in the Coats-Snowe Amendment, and "referrals" in the Weldon Amendment, it did not include any of these terms in § 300a-7(b), (c), or (d), which prohibit discrimination only on the basis of a refusal to "perform" or "assist in the performance" of a particular procedure. Congress knew how to draft legislation that would cover these activities in the health care conscience context when it wanted to, so HHS has no authority to define a statutory term in a manner that Congress chose to forego.

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HHS's definition of "assist in the performance" is also contrary to the common meaning of those terms. The dictionary defines "performance" as "the execution of an action" and "assist" as to give support or aid."[3] The Church Amendments prohibit discrimination for refusing to execute, support or aid in the execution of an abortion or sterilization procedure. 42 U.S.C. § 300a-7(c). If Congress intended to include all conduct that "further[s] a procedure," *see* 84 Fed. Reg. at 23263 (§ 88.2), it would have said so. Instead, Congress used the term "performance," which limits the statutory scope to the medical execution of the procedure.

The legislative history confirms that the Rule's "assist in the performance" definition extends far beyond Congress's intent. Senator Church explained that the amendments were "meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions . . . . There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." 119 Cong. Rec. 9597 (Mar. 27, 1973) (statement of Sen. Church). The Rule extends the Church Amendments far beyond this tailored approach to cover not just those individuals performing the procedures, but also

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[3]Performance, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/performance; *Assist*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/assist.

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to cover *anyone* taking *any* action with an "articulable connection" to a procedure—including the scheduler who keeps the calendar. 84 Fed. Reg. at 23186–87. By extending the Church Amendments far beyond their purpose, the Rule exceeded HHS's statutory authority. *See ACA Int'l v. F.C.C.*, 885 F.3d 687, 692, 697–99 (D.C. Cir. 2018).

"Discriminate" or "discrimination." None of the statutes that the Rule intends to implement define the term "discrimination." The ordinary meaning of the term is the "failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 286 (2011) (quoting Black's Law Dictionary 534 (9th ed. 2009)). The Rule exceeds the boundaries set in the statute by going beyond the ordinary meaning of the term, imposing special restrictions on employers that favor objecting employees at the expense of the timely and safe provision of health care services.

For example, employers are prohibited from asking before hiring whether an applicant has objections to services provided by the employer; must have a "persuasive justification" to ask employees if they are willing to perform an essential job function to which they might object; cannot create an accommodation that excludes a staff member from their "field[] of practice"; and must depend on an employee's willingness to accept an accommodation to avoid discrimination, regardless of the reasonableness of such accommodation. 84 Fed.

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Reg. at 23263 (§ 88.2). Health care entities could therefore be required to hire someone who cannot deliver health care services that are critical to the entity's mission, or risk sanction. The Rule's definition of "discrimination" is so broad that it impermissibly "command[s] that . . . religious concerns automatically control over all secular interests at the workplace." *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709 (1985).

b. The Rule conflicts with existing healthcare laws

Under the APA, courts must set aside agency action "in excess of statutory jurisdiction, authority, or limitations" or otherwise "not in accordance with law." 5 U.S.C. §§ 706(2)(A), (C). Where, as here, a plaintiff alleges that agency action is contrary to law, courts apply the framework established in *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Nw. Envtl. Advocates v. E.P.A.*, 537 F.3d 1006, 1014 (9th Cir. 2008). Under *Chevron*, the court "must give effect to the unambiguously expressed intent of Congress." 467 U.S. at 843. "If the statutory language is plain, [the court] must enforce it according to its terms." *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015).

The Rule is contrary to law and must be set aside because it violates the statutes HHS purports to interpret, including the ACA's non-interference mandate, the ACA's non-discrimination mandates, 42 U.S.C. § 18116, and EMTALA's mandate to provide emergency care, 42 U.S.C. § 1395dd. 5 U.S.C. § 706(2)(A); *Fed. Election Comm'n v. Democratic Senatorial Campaign Comm.*,

454 U.S. 27, 32 (1981) (holding that regulations "inconsistent with the statutory mandate or that frustrate the policy that Congress sought to implement" are invalid).

(1) The Rule is contrary to the ACA because it denies timely access to medical care, interferes with provider-patient communications, and undermines informed consent or medical ethics

In the ACA, Congress enacted a statutory section that preserves the sanctity and integrity of the patient-provider relationship by prohibiting interference by federal regulators. The Rule's creation of an overbroad right to withhold relevant information and misrepresent patient options violates section 1554 by "restrict[ing] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," "imped[ing] timely access to health care services," "interfere[ing] with communications regarding a full range of treatment options between the patient and the provider," "restrict[ing] the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," and "violat[ing] the principles of informed consent and the ethical standards of health care professions." 42 U.S.C. § 18114(1)–(4); *see Washington v. Azar*, __ F. Supp. 3d __, 2019 WL 1868362 (9th Cir. 2019), at *5–6, *rev'd sub nom.*

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California v. Azar, __ F.3d __, 2019 WL 2529259 (9th Cir. 2019).[4]

The Rule allows anyone "assist[ing] in the performance of any lawful health service" to deny care, including "counseling" or "referral," 84 Fed. Reg. at 23263, 23265. HHS expressly chose to promulgate the Rule without "regard to whether data exists on the competing contentions about its effect on access to services," contending that the Rule "represent[s] Congress's considered judgment that these rights are worth protecting even if they impact overall or individual access to a particular service, such as abortion." 84 Fed. Reg. at 23182.

But Congress cannot have intended that patients be placed in the untenable situation of not only being refused medically necessary care, but potentially never becoming aware of the fact that they were not counseled on the full range of options medically available to them. And yet the Rule allows doctors and their staff to withhold necessary information from patients that would allow them to make decisions for themselves—in violation of informed consent. It cannot be said that a patient is capable of making an informed decision about their health when they have not been counselled on all medically available options.

In some cases, doctors might not even be aware that a staff member has

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[4] On June 20, 2019, a motions panel of the Ninth Circuit stayed the preliminary injunction in *Washington v. Azar* pending appeal. Plaintiffs in that case, including the State of Washington, are currently seeking expedited en banc review, and merits briefing before the Ninth Circuit is still in progress.

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turned away care. The Rule also creates unreasonable barriers and impedes access to medical care by undermining Plaintiff's ability to provide for the delivery of critical health services in their institutions. Moss Decl. ¶ 8; Zahn Decl. ¶ 8; Broom Decl. ¶¶ 14, 17; Currey Decl. ¶¶ 17–19; Taylor Decl. ¶ 12. The Rule will interfere with the operations of health care systems and threaten delivery of patient care, particularly in emergency, rural, and end-of-life care settings. For the foregoing reasons, the Rule is in violation of Section 1554 of the ACA and unlawful.

(2) The Rule violates the ACA's anti-discrimination provisions

The Rule is also unlawful because it permits providers and other healthcare personnel to discriminate on the basis of sex and disability. Section 1557 of the ACA prohibits discrimination under any health program or activity on the basis of classifications listed in four federal civil rights statutes: Title VII of the Civil Rights Act of 1964 (race, color, and national origin); Section 504 of the Rehabilitation Act of 1973 (disability); Title IX of the Education Amendments of 1972 (sex), and the Age Discrimination Act of 1975 (age). 42 U.S.C. § 18116(a).

Whereas the 2008 rule confirmed that it did not authorize prohibited discrimination under federal civil rights laws, the present Rule contains no such assurance. *See* 73 Fed. Reg. 78072 at 78080 (Dec. 19, 2008) ("emphasiz[ing] that the health care conscience protection laws exist as one part of a number of federal laws that address discrimination on a variety of grounds, and that the actions

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described in the hypothetical situations that violate federal civil rights laws, continue to violate federal civil rights laws"). By contrast, in response to a comment that the Rule might impact referrals and counselling for LGBTQ, HHS did not disagree that the Rule would negatively impact such referrals and counselings. 84 Fed. Reg. at 23189. Instead, HHS stated that the Rule does permit discriminatory conduct against LGBTQ persons, depending on the "specific facts . . . circumstances . . . and particular claims." *Id.* The Rule's encouragement of discrimination violates ACA § 1557.

(3) The Rule violates the ACA's contraceptive coverage requirement

The ACA and the regulations implementing it require insurers to provide contraceptive coverage. 42 U.S.C. § 300gg-13(a)(4). The ACA exempts churches and religious orders from the contraceptive coverage mandate, but only provides an accommodation for certain non-church employers with religious beliefs that conflict with the use of contraceptives. *Id*. If employers invoke the accommodation, the responsibility to "provide contraceptive coverage for the organization's employees" falls to the insurer. *Id*. The accommodation recognizes the employers' "religious exercise while at the same time *ensuring that women covered by [their] health plans 'receive full and equal health coverage, including contraceptive coverage*.' " *Zubik v. Burwell*, 136 S. Ct. 1557, 1559 (2016) (per curiam) (emphasis added).

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The Rule interferes with ACA's contraceptive coverage mandate. It expands the Weldon Amendment's definition of the term "health care entity" to include a "plan sponsor," 84 Fed. Reg. at 23264 (§ 88.2), which effectively allows *any* employer who sponsors an insurance plan to object to providing coverage for contraception. Moreover, because the Rule's definition of "health care entity" also includes "health insurance issuers," an insurance plan can no longer be obligated to provide contraception coverage.

(4) The Rule violates EMTALA

Under EMTALA, a hospital cannot deny emergency medical care to patients with emergency medical conditions, explicitly including pregnant women where "the health of the woman or her unborn child" is "in serious jeopardy[.]" 42 U.S.C. § 1395dd(e)(1). A hospital can only "discharge its duty under EMTALA" by conducting an appropriate screening designed to identify "acute" and "severe" symptoms. *Eberhardt v. City of Los Angeles*, 62 F.3d 1253, 1258 (9th Cir. 1995). The Rule acknowledges a potential conflict with EMTALA, but merely states that "where EMTALA might apply in a particular case, the [HHS] would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible." 84 Fed. Reg. at 23188. The Rule contains no directive as to how or even whether emergency care is to be provided when it conflicts with the categorical refusal-of-care right that the Rule confers on employees. Instead, HHS will determine whether the hospital properly handled

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the objector's refusal of care on an ad hoc basis, based on "the facts and circumstances." *Id.* at 23263.

The uncertainty of the Rule, with the possibility of draconian sanctions for noncompliance, is utterly unworkable in practice, particularly in the context of a medical emergency. By purporting to extend rights to ambulance drivers among other emergency providers, 84 Fed. Reg. at 23263, without any express exception for emergencies, the Rule directly conflicts with EMTALA.

(5) The Rule violates the non-directive pregnancy counseling mandate applicable to Title X of the Public Health Service Act

"In 1970, Congress created the Title X program to address low-income individuals' lack of equal access to the same family planning services, including modern, effective medical contraceptive methods such as 'the Pill,' available to those with greater economic resources." *Washington v. Azar*, 2019 WL 1868362, *3.[5] HHS is directed to award grants to state or local governments and non-profit organizations for "family planning projects that offer a broad range of acceptable and effective family planning methods and services to patients on a voluntary basis, 42 U.S.C. § 300(a), creating a nationwide [network] of Title X health care providers." *Id.*

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[5]Again, a motions panel of the Ninth Circuit issued an order staying the preliminary injunction in this case. The State is seeking expedited rehearing en banc.

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Since 1996, Congress has passed annual appropriations acts applicable to HHS requiring that all pregnancy counseling within a Title X program must be nondirective. *Washington v. Azar*, 2019 WL 1868362, *6; Pub. L. No. 115-245 (*supra* n.1). Under this non-directive mandate, all recipients of Title X grant funds must ensure that counseling of each pregnant patient offers "information on all options relating to her pregnancy, including abortion." *Id.*; *see also* Program Requirements for Title X Funded Family Planning Projects[6] (incorporating *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs*, Morbidity and Mortality Weekly Report Vol. 63, No. 4 (April 25, 2014))[7] ("[i]f the patient indicates that the pregnancy is unwanted, she should be fully informed in a balanced manner about all options, including raising the child herself, placing the child for adoption, and abortion"); American Academy of Pediatrics & The American College of Obstetricians & Gynecologists (ACOG), Guidelines for Perinatal Care, p. 127 (7th ed. 2016)). Congress did not create a conscience-based right for the applicants for Title X grants to refuse to comply with the non-directive mandate.

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[6] *Available at* https://www.hhs.gov/opa/sites/default/files/Title-X-2014-Program-Requirements.pdf (last accessed June 23, 2019).

[7] *Available at* https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf (last accessed June 11, 2019).

ATTORNEY GENERAL OF WASHINGTON
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Yet, by allowing anyone participating in the performance of the health services to refuse to provide information about abortion or other types of care that pregnant patients may need, the Rule permits Title X providers to violate the Nondirective Mandate. This violates patients' rights under the statute to receive counseling that is not directive and does not selectively withhold medically relevant information.

c. The Rule is arbitrary and capricious

The Rule is arbitrary and capricious in numerous respects. Courts must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of a problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [made a decision that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

(1) The Rule's expansion of the scope of covered conduct makes the Rule arbitrary and capricious

As explained above, *infra* section III(B)(1)(a), the Rule unlawfully expands the reach of the statutes it claims to interpret by adopting definitions of statutory terms which unlawfully expand the reach of those statutes and which run counter to the evidence before HHS. Specifically, the definitions of "assist in

the performance," "discrimination," "health care entity," and "referral" create an unworkable situation for State agencies and health providers by dramatically expanding the universe of protected persons and prohibited conduct.

By expanding these definitions beyond Congressional intent, the Rule's full scope is vague and impossible to discern. Administrative action is arbitrary and capricious when it "'fails to articulate a comprehensible standard' for assessing the applicability of a statutory category." *ACA Int'l*, 885 F.3d at 700. The Rule's definition of "assist in the performance," for example, can mean any action with any "articulable connection" to furthering a procedure, which "*may* include counseling, referral, . . . or otherwise making arrangements . . . *depending on* whether aid is provided by such actions." 84 Fed. Reg. at 23263 (§ 88.2) (emphasis added). Federal funds recipients must guess which routine actions, procedures, or referrals at work "may" constitute "assistance" that will elicit a conscience objection. *Id.* at 23188. Could a customer service representative at an insurance company's hotline refuse to answer a customer's questions about covered services? Could a billing clerk at a hospital refuse to record and process certain procedures for payment? Could a provider's staff member refuse to submit samples for testing, resulting in a delay that makes them unusable? Under the Rule, each of these individuals (1) cannot be asked prior to hiring whether they can execute the core functions of their jobs without objection; (2) once hired, have no duty to voluntarily disclose any religious or

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moral objection to any aspect of their work; (3) object at any time to a job task with no advance notice and regardless of the effects on patient health; and (4) have a categorical right to reject any attempted accommodation as not "effective." And there will be no consequence to their employment.

Further, the administrative record put HHS on notice that its overreach will disrupt the effective delivery of health care services and dramatically undermine the safe and reliable provision of health care.[8] Courts have "not hesitated" to reverse agency decisions "when an agency ignores factual matters or fails to respond adequately to meritorious arguments raised in opposition to the agency's action." *Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 68 (D.D.C. 2016); *see League of Women Voters of the U.S. v. Newby*, 838 F.3d 1, 9–12 (D.C. Cir. 2016) (disregard for statutory requirement renders agency decision arbitrary).

(2) HHS's analysis of the costs and benefits of the Rule is counter to the evidence before the agency

The Rule is arbitrary and capricious because HHS relied on a flawed cost-

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[8] *See, e.g.*, Declaration of Paul Crisalli in Support of State of Washington's Motion for Preliminary Injunction (Crisalli Decl.), Ex. A (comment from Attorneys General of New York, *et al.*) at 7–9, 13–15; Crisalli Decl., Ex. B (comment from California Dep't of Justice) at 1, 6; Crisalli Decl., Ex. C (comment from N.Y. City Comm'n on Human Rights, *et al.*) at 1–4.

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benefit analysis, cited to benefits without any evidentiary basis, ignored extensive costs detailed in the record, and declined to quantify the costs of critical concerns, including the impact on access to care. Thus HHS "offered an explanation for its decision that runs counter to the evidence before the agency" and "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

Costs are a centrally relevant factor for agencies when deciding whether to regulate. *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707 (2015). But when "an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Nat'l Ass'n of Home Builders v. E.P.A.*, 682 F.3d 1032, 1040 (D.C. Cir. 2012).

Here, HHS relied on a regulatory impact analysis to analyze the Rule's costs and benefits, which is fatally flawed in three respects. First, HHS refused to quantify the costs of the Rule's impact on access to care—a critical problem when issuing a rule regulating health care entities relationships with patients. Commenters provided substantial evidence proving that the changes would drastically reduce access to health care, especially for vulnerable populations.[9]

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[9]*See, e.g.*, Crisalli Decl., Ex. D (comment from Am. Acad. of Pediatrics) at 3–14; Crisalli Decl., Ex. E (comment from Am. Coll. of Obstetricians & Gynecologists) at 2; Crisalli Decl., Ex. A (comment from Attorneys General of New York, *et al.*) at 18–20; Crisalli Decl., Ex. F (comment from Inst. for Policy Integrity) at 5–8.

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HHS refused to assess the Rule's impact, declaring the Rule should be implemented "without regard to whether data exists on the competing contentions about its effect on access to services." 84 Fed. Reg. at 23182. HHS thus declined to even analyze the concerns, deciding to implement the Rule anyway. The APA does not permit an agency to ignore such a central evidentiary question. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198–1203 (9th Cir. 2008); *see Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002).

Second, the benefits HHS uses to justify the Rule lack any support in the administrative record. An agency's decision is arbitrary and capricious where there is no evidence that the agency based its conclusion on any findings or data. *City of Los Angeles v. Sessions*, 293 F. Supp. 3d 1087, 1099–1100 (C.D. Cal. 2018).[10] HHS states that faith-based care providers would likely limit the scope of their medical practice if conscience rules are not in place, 84 Fed. Reg. at 23246–47, but its sole support is a 2009 survey of members of five religious medical groups conducted by the Christian Medical Association discussing the

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[10] HHS asserts the rule has the benefit of providing a centralized office for individuals and institutions to file complaints, 84 Fed. Reg. at 23250, but this office and function already exist. 73 Fed. Reg. at 78101. Relying on a claimed benefit that already exists is arbitrary. *New England Coal. on Nuclear Pollution v. Nuclear Regulatory Comm'n*, 727 F.2d 1127, 1130-31 (D.C. Cir. 1984).

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possible rescission of the 2008 Rule. *See id.* at 23246–48 & n.316. But that rescission took place in 2011, and HHS made no effort to examine whether the intervening eight years showed *any* effect on the scope of practice of faith-based professionals.[11] *See Nat'l Fuel Gas Supply Corp.*, 468 F.3d 831, 841 (D.C. Cir. 2006) (action vacated for lacking evidence of key factual conclusion).

Similarly, the source for HHS's assertion that the Rule would "decrease . . . departures from the field" because "a certain proportion of decisions by currently practicing health providers to leave the profession are motivated by coercion or discrimination based on providers' religious beliefs or moral convictions," is the same online survey conducted by the Christian Medical Association. 84 Fed. Reg. at 23247 & n.322. The survey contains no support for this conclusion. *Id.* HHS's conclusion that the Rule will *increase* available providers by removing barriers, 84 Fed. Reg. at 23246–47, lacks any evidentiary support. The contention defies logic because an influx of objecting providers will only serve to further strain non-objecting providers who will need to cover greater numbers of people with objections.

Third, the Rule is arbitrary and capricious because HHS understates the

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[11]In preliminarily enjoining a different HHS rule that relied on the same survey, the district court described the "myriad" "flaws" in relying on this poll. *California v. Azar*, 2019 WL 1877392 at *34, *rev'd on other grounds* __ F.3d __, 2019 WL 2529259 (9th Cir. 2019).

costs of compliance. *See Mingo Logan Coal Co. v. E.P.A.*, 829 F.3d 710, 732–33 (D.C. Cir. 2016) (consideration of costs is an essential component of reasoned decisionmaking under the [APA]"); *see Michigan v. E.P.A.*, 135 S. Ct. at 2707–08. For instance, HHS found that the Rule "may add 65 to 130 new persons and entities" who were not already covered by the 2011 Rule, an increase of only approximately 0.02%. 84 Fed. Reg. at 23233–35 & tbl. 2. But this estimate ignores that the Rule dramatically expands the term "health care entity" to include all "health care personnel" and "any other health care provider or health care facility" as well as plan sponsors, plan issuers, and third-party administrators. 84 Fed. Reg. at 23264 (§ 88.2). The agency record establishes that the number of covered entities is far larger than HHS's estimate and the attendant compliance costs are much higher. Agency action is unreasonable when the agency action's factual premise is contradicted by its own record. *City of Kansas Cit., Mo. v. Dep't of Housing & Urban Dev.*, 923 F.2d 188, 194 (D.C. Cir. 1991).[12]

(3) The assurance and certification requirements are arbitrary and capricious

The assurance and notification requirements are arbitrary and capricious

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[12]The estimate that each covered entity will need only a one-time burden of two hours to familiarize themselves with the Rule lacks factual support or common sense when the Rule is over 100 pages in the Federal Register, has 400 footnotes, and implements 30 federal statutory provisions.

because HHS does not explain any awareness that it is changing its position. The Rule imposes new, improper requirements that recipients submit written assurances and certifications that contractually obligate the recipient and their sub-recipients to abide by the Rule. *See* 84 Fed. Reg. at 23269. But HHS fails to recognize that it previously concluded such requirements were unnecessary. *See* 84 Fed. Reg. at 23213–16; 83 Fed. Reg. 3880, 3896–97 (Jan. 26, 2018); 76 Fed. Reg. 9968, 9974 (Feb. 23 2011). Although HHS may change its position during rulemaking, it must explain its awareness of the change. *Fox Television Stations, Inc.*, 556 U.S. at 515; *See also R.F.M. v. Nielsen*, 365 F. Supp. 3d 350, 381 n.17 (S.D.N.Y. 2019).

2. Washington is likely to succeed on the merits of its separation of powers argument

Because the Constitution vests the spending power in Congress, the Executive Branch "does not have unilateral authority to refuse to spend . . . funds" already appropriated by Congress "for a particular project or program." *In re Aiken County*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013). Although Congress may delegate some discretion to the Executive Branch to decide how to spend appropriated funds, *see Clinton v. City of New York*, 524 U.S. 417, 488 (1998), that discretion is cabined by the scope of the delegation, *City of Arlington v. F.C.C.*, 569 U.S. at 296.

Congress has clearly attached specific conditions to the acceptance of specific sources of funds, and not others. *E.g.*, 42 U.S.C. § 300a-7(c) (identifying

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specific grants to which certain of the Church Amendments' protections apply). For example, the Coats-Snowe Amendment prohibits discrimination related to training in the performance of abortion in specifically-defined "health care entities," 42 U.S.C. § 238n(c)(2), while ACA Section 1553 prohibits discrimination against a different category of "health care entities" on the basis of a refusal to provide services that assist in assisted suicide, 42 U.S.C. § 18113.

But the Rule redefines key statutory terms, grants HHS broad investigative and compliance authority, and gives HHS the unilateral authority to terminate billions of dollars in Congressionally appropriated federal funds. *Id.* at 23263–64, 23269–71 (§§ 88.2, 88.4, 88.6, 88.7). HHS has no authority to rewrite the statutes Congress enacted in this way. *City & County of San Francisco v. Sessions*, 372 F. Supp. 3d 928, 941 (N.D. Cal. 2019) (quoting *I.N.S. v. Chadha*, 462 U.S. 919, 959 (1983)) ("[t]he Constitution gives an 'unmistakable expression of a determination that legislation by the national Congress be a step-by-step, deliberate and deliberative process.'"). Nor does HHS have the authority to refuse to spend funds Congress appropriated for a particular program. *In re Aiken County*, 725 F.3d at 261 n.1 (citing *Train v. City of New York*, 420 U.S. 35, 42–45 (1975)). In so doing, the Rule exceeds the HHS's discretion to attach conditions on the use of federal funds and violates the constitutional separation of powers.

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3. Washington is likely to succeed on the merits of its spending clause argument

Even if HHS had been delegated the authority to refuse to spend funds appropriated by Congress—which it hasn't—and even if Congress itself had imposed the draconian conditions on the funds—which it didn't— the Rule would be unconstitutional under the Spending Clause. Article I, section 8, clause 1 of the United States Constitution, known as the Spending Clause, states that "Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and provide for the common defense and general welfare of the United States." Under the Spending Clause, an agency must not impose conditions on federal funds that are (1) so coercive that they compel (rather than encourage) recipients to comply, (2) ambiguous, (3) retroactive, or (4) unrelated to the federal interest in a particular program. *Nat'l Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 575–78 (2012); *South Dakota v. Dole*, 483 U.S. 203, 206–08 (1987). The Rule violates all of these limitations.

a. The Rule is coercive

The Rule threatens to strip all federal funding if OCR deems the Rule violated. This is an unconstitutionally coercive "gun to the head." *NFIB*, 567 U.S. at 581; Schaub Decl. ¶ 6 (Washington annually receives over $10.5 billion in federal funding from HHS, $1.1 billion from DOE, and $225 million from DOL); Broom Decl. ¶ 5 (UW annually relies on $1.167 billion in HHS federal funding); Currey Decl. ¶¶ 6–7 (DOC is reliant on Medicaid to pay approximately $8.9

million dollars annually in prisoner hospital bills); Taylor Decl. ¶ 6 (WSU relied on over $100 million annually in grants for research to improve human health, serve underserved populations, and for student Medicaid reimbursements); Harris Decl. ¶ 24 (DOH is the sole recipient of $4 million annually in Title X funding); Lindeblad Decl. ¶ 2 (HCA received $8.4 billion in federal funding in fiscal year 2018); Moss Decl. ¶ 11 (DSHS relies on over $2.5 billion in federal funding each year). The loss of funding leaves the State "with no real option but to acquiesce." *NFIB*, 567 U.S. at 581–82. Under existing precedent, the Rule violates the Spending Clause by threatening to "penalize [recipients] that choose not to participate in [a] new program by taking away their existing [] funding." *NFIB*, 567 U.S. at 585, and by permitting the termination of the State's funding based on the conduct of third-party sub-grantees. *See Gebser v. Lago Vista Ind. Sch. Dist.*, 524 U.S. 274, 287–88 (1998) (focuses is whether private party was on notice that it could cause liability, even acting in good faith); *Oona v. Santa Rosa Cty. Schs.*, 890 F. Supp. 1452, 1464-66 (N.D. Cal. 1995) (damages for good faith violations inappropriate when laws are under Spending Clause).

The expanded scope of individuals and entities that can claim conscience objections, coupled with the breadth of acts that can be objected to, exponentially multiplies the risk borne by the State, and, in turn, the Rule's coercive effect. Given the billions of dollars in funding at stake, the loss of which would decimate the delivery of health care to the State, the Rule constitutes "economic

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dragooning" rather than "relatively mild encouragement" to comply. *See NFIB*, 567 U.S. at 581–82. The State is likely to succeed in showing that the Rule is unconstitutionally coercive.

b. The Rule is vague and ambiguous

Congress may condition the States' receipt of federal funds, but "must do so unambiguously" so that the State can exercise its choice to accept federal funds knowingly and voluntarily. *Dole*, 483 U.S. at 207. The Rule does not meet this requirement, using vague terms, defining terms inconsistently with the underlying federal statutes or long-standing usage, imposing new conditions on the receipt of federal funds, and inadequately describing the actions that will lead to sanctions.

The Rule purports to allow any "health care personnel" to refuse to provide medical care or to perform any action that has an "articulable connection" to furthering a procedure on the basis of religious, ethical, or "other reasons," without providing any information to the patient about the patient's medical condition or treatment options. 84 Fed. Reg. at 23263. As discussed *infra* at III(B)(1)(a), the definitions provided are inconsistent with the underlying statutes. HHS compounds this ambiguity by refusing to respond to comments that attempt to clarify scope, instead saying that the issues must be resolved on a case-by-case basis depending on the facts and circumstances. *Id.* at 23188, 23189, 23205. Where, as here, HHS refuses to make the conditions clear, the State

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cannot make knowing, dependable and proportionate choices about (1) how it should treat employees' denials of care and (2) whether it should change its own policies to comply with the Rule.

c. The Rule lacks a nexus to the federal funds it threatens

Finally, the Spending Clause requires that funding conditions "bear some relationship to the purpose of the federal spending," *New York v. United States*, 505 U.S. 144, 167 (1992), and be "reasonably calculated" to address the "particular . . . purpose for which the funds are expended," *Dole*, 483 U.S. at 208–09. The conditions imposed by the Rule "might be illegitimate if they are unrelated to the federal interest in particular national projects or programs." *Id*. at 207 (quotations omitted). The Rule jeopardizes funding for the State's labor and educational programs—programs with no relationship whatsoever to the Rule's health care conscience restrictions. *See infra* section II(C)(4). The Rule violates the Spending Clause.

4. Washington is likely to succeed on the merits of its establishment clause argument

The Establishment Clause bars official conduct that favors one faith over others, has the primary purpose or primary effect of advancing or endorsing religion, or coerces religious belief or practice. *See, e.g.*, *McCreary County v. ACLU of Ky.*, 545 U.S. 844, 860 (2005); *Santa Fe Indep. Sch. Dist. v. Doe*, 530 U.S. 290, 302 (2000). The Rule officially prefers the religious beliefs of objectors over the rights and beliefs of providers and patients, and it coerces religious

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exercise by requiring providers and patients to act in accordance with objecting employees' religious beliefs. The Rule's favoritism toward religious beliefs invoked by objecting employees do not survive the applicable strict scrutiny, *see Larson v. Valente*, 456 U.S. 228, 246 (1982), or any, scrutiny because, among other reasons, there are obvious less-restrictive alternatives for accommodating objecting employees, including existing policies that Washington, its sub-recipients, and other healthcare entities nationwide already employ.

a. The Rule impermissibly burdens patients and third parties with employees' religious beliefs

The Establishment Clause prohibits religious exemptions or accommodations by government that would have a "detrimental effect on any third party," *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2781 n.37 (2014), because these accommodations impermissibly prefer the religion of those who are benefited over the beliefs and interests of those who are not. *See, e.g., Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 15, 18 (1989) (plurality opinion); *Caldor*, 472 U.S. 703 (invalidating law requiring employers to accommodate people observing the Sabbath in all instances). In evaluating this well settled authority, courts must "account [for] the burdens a requested accommodation may impose on nonbeneficiaries" and ensure that the accommodation does not "override other significant interests." *Cutter v. Wilkinson*, 544 U.S. 709, 720, 722 (2005). Washington has laws, consistent with existing federal law, that ensure that patients can receive their full options of health care while respecting

employees' religious beliefs. *See infra* section II(B). The Final Rule undermines essential patient protections by inviting employees, contractors, and volunteers of health care institutions to deny care to patients based on religious, moral, or other objections to the treatment or to the characteristics or circumstances of the patient, without regard to the harms they will impose on patients and providers.

By hamstringing Washington and its health care institutions' ability to make appropriate accommodations, refusals will result in in delays or denials of care. As explained in Section III(B)(3)(a), *infra*, the Rule's elevation of certain religious rights over all else places Washington and its citizens in an impossible bind—whether Washington complies with the Rule or chooses to forgo billions of dollars in federal funding, the public health will be unreasonably burdened and suffer significant harm. For these foregoing reasons, the Rule violates the Establishment Clause." *Caldor*, 472 U.S. at 709.

b. The Rule impermissibly coerces patients and providers to adhere to government favored religious practices

The "Constitution guarantees that government may not coerce anyone to support or participate in religion or its exercise." *Lee v. Weisman*, 505 U.S. 577, 587 (1992). But the Rule allows individual employees to dictate whether and how patients receive health care based on their own personal views. That is true even when those beliefs are expressly contrary to the mission of the agencies and institutions providing the care or the patients' own beliefs. *See e.g.* Saxe Decl.

¶¶ 13–15; Lindeblad Decl. ¶¶ 3, 6, 13; Harris Decl. ¶¶ 3, 52–54. This violates the Establishment Clause.

C. Washington Will Suffer Irreparable Harm Absent Preliminary Relief

The harm analysis "focuses on irreparability, irrespective of the magnitude of the injury." *California v. Azar*, 911 F.3d at 581 (internal quotation marks omitted). The Rule is likely to cause at least six types of irreparable harms to Washington.[13]

1. The Rule will harm Washingtonians

The Rule will deny Washingtonians timely, medically necessary care and information about reproductive health, LGBTQ health, and end-of-life care. *See e.g.,* Kreidler Decl. ¶ 4; Lindeblad Decl. ¶ 13; Moss Decl. ¶¶ 21, 34. Injury to residents' health and well-being irreparably harms the State itself. *California v. Health & Human Servs.*, 281 F. Supp. 3d 806, 830 (N.D. Cal. 2017), *aff'd in pertinent part sub nom. California v. Azar*, 911 F.3d 558 (finding irreparable injury based in part on "what is at stake: the health of Plaintiffs' citizens and Plaintiffs' fiscal interests"); *See Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 828 (E.D. Pa. 2019) (same).

The Rule not only allows medical providers to refuse to provide medically necessary care, it allows medical providers to refuse to counsel their patients on

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[13] "That [Washington] promptly filed an action following the issuance of the [Rule] also weighs in [its] favor" for the irreparable harm analysis. *Id.*

the medically and scientifically complete range of care and options available to them. It is impossible for a patient to make an educated and informed decision when they have not been counseled on all the options available to them. For this reason doctors and ethicists consider the Rule an affront to the Hippocratic and Nightingale oaths because doctors and nurses will be allowed to provide incomplete, biased, dishonest, and medically-inaccurate care to patients. *See* Zahn Decl. ¶¶ 6–15; Kimelman Decl. ¶¶ 9–14. By doing so, a provider indisputably fails "in their fundamental duty to enable patients to make decisions for themselves." Declaration of Dr. Judy Kimelman in Support of State of Washington's Motion for Preliminary Injunction (Kimelman Decl.) ¶ 14. And, without even knowing it, patients will receive limited, incomplete care.

The Rule particularly affects patients with limited or constrained options for medical services. For instance, in rural areas, there are clinics with small staffs. If a doctor, pharmacist, or staff member exercises a conscience objection under the Rule, the patient would have to find alternative care, sometimes hundreds of miles away, or they will choose not to seek care at all, which will have long-term health consequences. *See, e.g.,* Saxe Decl. ¶ 14; Kreidler Decl. ¶ 5; Lindeblad Decl. ¶ 13. Students at Washington colleges whose only health-care options are through the campus, like at WSU and UW, could receive limited care based on the religious beliefs of the providers. Taylor Decl. ¶¶ 11–13. Even in prisons, inmates will be subject to the beliefs of the limited

staff, who might not only might, but already have refused to provide care. Currey Decl. ¶¶ 11–18. By complying with the Rule, the State could fail in its obligation to treat those in its care. Currey Decl. ¶¶ 10, 18. For some recipients, there is no choice but to refuse federal funding altogether. The Rule conflicts with Washington's informed consent requirements, the non-directive mandate, and State laws. Negative health consequences and societal costs will result.

2. The missions of Washington's agencies and medical institutions will be harmed and compromised

The Rule will irreparably harm the core missions and values of Washington's agencies and medical institutions. *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013) (a showing of "ongoing harms to []organizational missions" will establish irreparable harm); *League of Women Voters*, 838 F.3d at 9 (irreparable harm was established when a primary mission was more difficult to accomplish). Numerous Washington agencies and medical institutions, each of which aim to safeguard the health and wellbeing of Washingtonians, will be unable to perform their core missions. *See e.g.*, Saxe Decl. ¶¶ 13–15; Lindeblad Decl. ¶¶ 3, 6, 13; Harris Decl. ¶¶ 3, 52–54.

As discussed, *infra* Section II(D), the Washington Pharmacy Quality Assurance Commission would have to repeal or modify its rules requiring pharmacies to fill prescriptions, thereby "heavily [undermining] the Commission's duty to the public," and resulting in "a strong likelihood of harm[] [to] the health, safety and welfare of the citizens of the State of Washington."

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Saxe Decl. ¶¶ 14–15. The Rule will impact HCA's mission to provide healthcare for the 1,812,000 Apple Health enrollees. Lindeblad Decl. ¶ 3, 6, 13. And the Rule will likely cripple the ability of DOH's sub-recipients to hire new staff because an important aspect of this work is providing unbiased reproductive health advice on potentially controversial subjects. Harris Decl. ¶¶ 52–54. If DOH sub-recipients cannot ask upon hire whether the applicant would be able to provide these services, the sub-recipients could ultimately be unable to provide the services. *Id*. ¶ 54. This will have significant negative impacts to DOH's mission to ensure citizens have access to family planning services. *Id*. ¶¶ 51–52.

3. Washington will be preempted from enforcing its longstanding laws safeguarding patient care

The Rule preempts Washington laws and impedes Washington's ability to enforce its legal code. This is sufficient to establish irreparable harm. *See California v. Azar*, 911 F.3d at 581 (a federal rule's limits on a State's enforcement abilities can create irreparable harm). The Rule preempts Washington state laws that balance conscience rights with a patient's right to medical care and information. 84 Fed. Reg. at 23272 (the Rule does not preempt laws that are "equal or more protective of religious freedom," than the Rule); *id.* at 23272 (directing that the Rule be given the broadest possible construction of religious freedom "to the maximum extent permitted."). HHS could argue that Washington is unable to take action against a hospital that refused to provide emergency contraception to a victim of sexual assault in violation of

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Washington's emergency contraception law, Reproductive Privacy Act, and Charity Care Law. Wash. Rev. Code 70.41.350 (requiring emergency rooms to provide emergency contraception as a treatment option to victims of sexual assault); *see also* Washington's Reproductive Privacy Act, Wash. Rev. Code 9.02.100(4),.110 (prohibiting the state from discriminating against, denying, or interfering with a woman's "right to choose to have an abortion prior to viability of the fetus, or to protect her life or health."); and Charity Care Law, Wash. Rev. Code 70.170.060 (requiring hospitals to provide care to a patient with an emergency medical condition or in active labor). HHS could find that the State violated the Rule because it disciplined clerks that refused to file or transfer a patient's end of life and advance directive requests, unbeknownst to anyone. Wash. Rev. Code 70.122.060(2) (imposing a duty to counsel on advanced directives); Wash. Rev. Code 70.245.190(d) (requiring that an objecting provider transfer the medical records of patients seeking end-of-life care upon request).

HHS could also argue that Washington is powerless to enforce its regulations ensuring that pharmacies fill lawful prescriptions. Wash. Admin. Code 246-869-010 (requiring pharmacies "to deliver lawfully prescribed drugs or devices to patients and to distribute drugs and devices approved by the U.S. Food and Drug Administration for restricted distribution by pharmacies . . . in a timely manner consistent with reasonable expectations for filling the prescription."). Or the Attorney General could be prevented from enforcing state

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civil rights laws against health care providers who refused to provide medically indicated services to gay or transgender patients. 2019 Wash. Sess. Laws, ch. 399, § 1(3) (prohibiting programs regulated by Washington's Health Care Agency from discriminating based on gender identity or expression).

HHS could threaten Washington with the loss of over $10 billion in funding if the State does not acquiesce, which would force Washington to choose between the very existence of its Medicaid and children's health insurance programs and enforcing Washington's civil rights laws that protect patient access to medical care and medicine.

4. Washington will incur substantial and uncompensable costs

In addition to the billions in federal funds Washington uses for an array of essential services, Washington also devotes its State resources to supplement and administer the programs connected to the federal funds. Those agencies and programs will have to expend funds to evaluate how to implement the Rule, to implement changes because of the Rule, and to continually oversee compliance with the Rule. There is no new funding source for these new costs, so the agencies and programs will likely have to reduce services or cut programs to cover them.

Unless the Rule is enjoined, agencies, programs, and providers will have to conduct analyses of their policies, procedures, and forms, including, among other things: evaluating processes in emergency rooms and operating rooms to allow for conscience objections, evaluating employee manuals and handbooks on

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hiring and firing policies with regard to the conscience objection, and evaluating complaint procedures for conscience objections. Broom Decl. ¶ 12; Taylor Decl. ¶¶ 13–14; Currey Decl. ¶¶ 20–23. State agencies estimate that the costs to undergo these evaluations alone will be in the millions. The agencies will also have to spend millions of dollars to implement the Rule. Broom Decl. ¶ 12; Taylor Decl. ¶¶ 13–14; Currey Decl. ¶¶ 20–23. In addition to drafting new policies and employee handbooks, agencies and the providers will have to create new systems, hiring additional staff to accommodate another's conscience objection, and training regarding the new requirements. Broom Decl. ¶ 12; Taylor Decl. ¶¶ 13–14; Currey Decl. ¶¶ 20–23. After implementing the Rule, there are added costs by remaining in compliance and monitoring the compliance of sub-recipients. *See, e.g.*, Broom Decl. ¶ 12; Taylor Decl. ¶¶ 13–14; Currey Decl. ¶¶ 20–23. Providers with conscience objectors will have to hire additional staff in order to provide the services to the patients. In some cases where the providers have small staffs, like in rural areas or in the prison system, this might mean that a provider has to double its staff to accommodate the objection. Currey Decl. ¶¶ 20–23. The State expects the costs for additional staff and oversight to be in the billions. There is no established funding source to cover any of these costs.

5. The Rule threatens loss of over $10 billion in funding

Washington receives over $10.5 billion in federal funding from HHS, U.S. Department of Education, and U.S. Department of Labor, all of which is placed

in jeopardy by the Rule. Declaration of Michael Schaub in Support of State of Washington's Motion for Preliminary Injunction (Schaub Decl.) ¶ 6. This is no idle threat. As discussed, the Rule is vague and inconsistent with other federal and state laws, while creating more conscience objectors and more potential conscience objections. A provider could take a good faith action which OCR subsequently defines as discriminatory. The effects would be devastating to the State, not only because of the loss of funding but also because of the loss of services impacted by immediate, harsh budget cuts.

6. Constitutional violations are irreparable harms

Finally, the Rule's constitutional violations establish irreparable harm. *See Melendres v. Arpaio*, 695 F.3d 990, 1002 (9th Cir. 2012) ("It is well established that the deprivation of constitutional rights 'unquestionably constitutes irreparable injury.'") (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). As explained above, the Rule violates the constitution.

D. Equity and the Public Interest Strongly Favor an Injunction

When the government is a party, the final two *Winter* factors merge. *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). "There is generally no public interest in the perpetuation of unlawful agency action. To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *League of Women Voters*, 838 F.3d at 12 (citations and internal quotation marks

omitted). Here, the balance of equities and public interest strongly favor an injunction. Preserving the status quo will not harm Defendants, and refraining from enforcing the Rule will cost them nothing. *See Diaz v. Brewer*, 656 F.3d 1008, 1015 (9th Cir. 2011) (court may waive Rule 65(c) bond requirement).

E. Relief Requested

For all the reasons above, the State of Washington requests that this Court preliminarily enjoin the Rule. *See, e.g.*, *Regents of the Univ. of Cal. v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476, 511–12 (9th Cir. 2018); *City of Los Angeles v. Sessions*, 293 F. Supp. 3d 1087, 1100–01 (C.D. Cal. 2018) (enjoining rule nationwide to ensure "even playing field" in competition for federal grants). Alternatively, and pursuant to the same standard, the State requests that the Court stay the rule's effective date during the pendency of this litigation pursuant to 5 U.S.C. § 705. *Cf. Bauer v. DeVos*, 325 F. Supp. 3d 74, 104–05 (D.D.C. 2018). The State requests a ruling prior to the effective date of 12:00 a.m. on July 22, 2019.

IV. CONCLUSION

For all the reasons above, the State of Washington requests that the Court preliminarily enjoins Defendants from implementing or enforcing the Rule.

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RESPECTFULLY SUBMITTED this 24th day of June, 2019.

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System which will serve a copy of this document upon all counsel of record.

DATED this 24th day of June, 2019, at Seattle, Washington.

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