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7 **UNITED STATES DISTRICT COURT**
8 **EASTERN DISTRICT OF WASHINGTON**
AT YAKIMA

9 STATE OF WASHINGTON,

10 Plaintiff,

11 v.

12 ALEX M. AZAR II, et al.,

13 Defendants.

NO. 1:19-cv-03040-SAB

STATE OF WASHINGTON’S
MOTION FOR PRELIMINARY
INJUNCTION

NOTED FOR: April 25, 2019
With Oral Argument at 10:00 a.m.

14 NATIONAL FAMILY PLANNING
15 & REPRODUCTIVE HEALTH
ASSOCIATION, et al.,

16 Plaintiffs,

17 v.

18 ALEX M. AZAR II, et al.,

19 Defendants.
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1 **I. INTRODUCTION AND RELIEF REQUESTED**

2 On March 4, 2019, Defendants (collectively, “HHS”) issued a Final Rule
3 that will destroy almost 90% of Washington’s statewide family planning
4 network. Contrary to Congress’s directive that HHS use grant funds under Title X
5 of the Public Health Service Act to establish projects that make “comprehensive
6 voluntary family planning services readily available to all persons desiring such
7 services,” under the Final Rule the number of Washington counties *without* a
8 Title X provider will jump from five to 21. This will leave low-income patients
9 in more than half of Washington’s counties without ready access to Title X family
10 planning services.

11 The State of Washington moves for a preliminary injunction prohibiting
12 HHS from implementing the Final Rule, which is scheduled to go into effect on
13 May 3, 2019. The Final Rule makes drastic and unlawful changes to five decades
14 of regulations implementing Title X, the nation’s family planning program for
15 low-income individuals. The Final Rule violates *three* controlling statutes, and is
16 arbitrary and capricious for a host of reasons. It must be enjoined to prevent
17 devastating harm to the State of Washington’s family planning network, and the
18 tens of thousands of patients who depend on it.

19 First, the Final Rule violates Congress’s mandate that all pregnancy
20 counseling in a Title X program “shall be nondirective” (the “Nondirective
21 Mandate”), which is included in the appropriations act that funds HHS through
22

1 September 2019 (and every annual appropriations act since 1996). Contrary to
2 the Nondirective Mandate, the Final Rule requires that *all* pregnant patients
3 receive directive referrals for prenatal care, prohibits referrals for abortion
4 (including at the patient’s request or when medically indicated), and permits
5 clinic staff at their discretion to give only directive counseling that pushes
6 patients toward carrying the pregnancy to term.

7 Second, the Final Rule violates section 1554 of the Patient Protection and
8 Affordable Care Act (ACA) in a number of different respects. It mandates strict
9 and costly separation of abortion-related speech and services from Title X-funded
10 services—not just financially, but physically—which, along with the coercive
11 pregnancy counseling requirements and other new provisions, will force out the
12 Title X clinics comprising 89% of Washington’s statewide network, leaving
13 low-income patients without access to services. The few clinics able and willing
14 to stay in the program will have to provide substandard care that omits accurate
15 medical information needed for informed decisionmaking and steers patients
16 toward the government’s preferred treatment option. Both outcomes violate
17 section 1554, which prohibits the Secretary from promulgating “any” regulation
18 that delays or creates barriers to medical care, interferes with patient–provider
19 communications, or violates principles of informed consent and medical ethics.

20 Third, the Final Rule violates Title X, as its effect fundamentally betrays
21 the statute’s central purpose: equalizing access to modern, high-quality, effective
22

1 contraception and other family planning services, regardless of a person's
2 economic condition. Forcing highly qualified and demonstrably successful
3 providers out of Washington's Title X program (based on care they provide
4 *independent* of the program) will inevitably reduce access to care, worsen health
5 outcomes, and hurt the very people the statute was intended to help. In addition,
6 the coercive counseling requirements violate the statutory command that receipt
7 of Title X services and information be strictly "voluntary." Furthermore, the Final
8 Rule exceeds HHS's authority and is arbitrary and capricious. In its single-
9 minded pursuit of policy goals unrelated to Title X, HHS ignored extensive
10 evidence in the record and failed to meaningfully respond to a host of public
11 comments, including unanimous opposition from leading medical associations.

12 The Final Rule is an executive overreach aimed at implementing policy
13 objectives disconnected from Title X. An agency cannot enact new policies
14 through a rulemaking that ignores or unrecognizably twists the meaning of
15 controlling statutes, or that brushes aside extensive evidence of the harm it will
16 cause. Agencies are strictly bound by laws duly enacted by Congress—and here,
17 Congress has spoken clearly, consistently, and repeatedly.¹

18
19 ¹ In addition to these consolidated cases, five other cases challenging the
20 Final Rule have been filed: Nos. 19-cv-217, 19-cv-318 (D. Or.);
21 Nos. 19-cv-1184, 19-cv-1195 (N.D. Cal.); No. 19-cv-100 (D. Me.).

1 **II. STATUTORY AND FACTUAL BACKGROUND**

2 **A. Overview of Title X and Washington’s Program**

3 Title X² is the nation’s safety-net family planning program for low-income
4 individuals. Through grants to states like Washington and other qualifying
5 entities, Title X funds “projects” or “programs” nationwide that offer a “broad
6 range of acceptable and effective family planning methods and services[.]”³ Title
7 X programs offer patients a wide selection of contraceptive methods and services;
8 testing for sexually transmitted infections (STIs) and human immunodeficiency
9 virus (HIV); cancer screenings; pregnancy testing and counseling; and referrals
10 for out-of-program care.⁴ Per section 1007 of the statute, the acceptance of all
11 Title X services and information must be strictly “voluntary.”⁵ Per section 1008,
12 Title X funds may not be used for “abortion as a method of family planning.”⁶

13 Title X’s primary purpose is to equalize access to modern, effective
14

15
16 ² 42 U.S.C. § 300 *et seq.*

17 ³ *Id.* § 300(a).

18 ⁴ *Id.*; 42 C.F.R. § 59.5(a).

19 ⁵ 42 U.S.C. § 300a-5.

20 ⁶ *Id.* § 300a-6. Congress has made clear that section 1008 is consistent with
21 requiring that Title X pregnancy counseling be nondirective. *See infra* at 6–7.
22

1 contraception to help women avoid unplanned and unwanted pregnancies.⁷ The
2 statute was passed with strong bipartisan support in 1970 in response to a growing
3 body of evidence that, due to low-income women’s lack of access to effective
4 contraception, they had less control over their reproduction than more affluent
5 women, creating adverse health and economic outcomes.⁸ First among Title X’s
6 stated purposes is “to assist in making comprehensive voluntary family planning
7 services readily available to all persons desiring such services”; a related goal
8 was to “improve the effectiveness of family planning service programs” in
9 helping people determine freely the number and spacing of their children.⁹

10 The Washington State Department of Health (DOH) is the sole grantee¹⁰
11 of Title X funds in Washington and runs a statewide program pursuant to state
12 law, overseeing a network of 16 subrecipient organizations operating 85 clinic
13

14 _____
15 ⁷ See *id.* § 300; ECF No. 1 (Compl.) ¶¶ 22–26.

16 ⁸ *Id.* ¶¶ 19–21.

17 ⁹ Pub. L. No. 91-572, § 2, 84 Stat. 1504 (1970).

18 ¹⁰ Washington has standing to sue as a grantee, *see, Nat’l Family Planning*
19 *& Reprod. Health Ass’n, Inc. v. Sullivan*, 979 F.2d 227, 239 (D.C. Cir. 1992),
20 and to vindicate its sovereign, quasi-sovereign, and proprietary interests, *Alfred*
21 *L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 600–07 (1982).
22

1 sites.¹¹ Approximately one third of the program is funded through Title X grants,
 2 while the remainder is State-funded.¹² This integrated, jointly funded program
 3 served over 91,000 low-income patients in 2017 (57% of whom were at or below
 4 the federal poverty level), saving over \$113 million in health care costs and
 5 helping women avoid over 18,000 unintended pregnancies that year alone.¹³

6 **B. Other Controlling Statutes**

7 HHS is authorized to issue regulations implementing Title X, subject to
 8 statutory limitations on its rulemaking authority found in Title X and elsewhere.¹⁴
 9 One such limitation is the Nondirective Mandate included in decades' worth of
 10 annual appropriations acts.¹⁵ The Department of Health and Human Services
 11 Appropriations Act, 2019, which funds HHS through September 2019, provides
 12 that all Title X pregnancy counseling "shall be nondirective[.]"¹⁶

13 _____
 14 ¹¹ Harris Decl. ¶ 14; [WA cmt.](#) at 4; RCW 43.70.040(5). For the Court's
 15 convenience, citations to public comments in the rulemaking record are both
 16 hyperlinked and attached to the Beneski Declaration as Exhibit 1.

17 ¹² Harris Decl. ¶ 24.

18 ¹³ Harris Decl. ¶¶ 26, 33; [WA cmt.](#) at 5.

19 ¹⁴ *See* 42 U.S.C. §§ 300–300a-4.

20 ¹⁵ Compl. ¶ 49 n.15 (citing appropriations acts 1996–2018).

21 ¹⁶ Pub. L. No. 115-245.

22

1 Another limitation on HHS’s authority is section 1554 of the ACA, which
2 provides that the Secretary “shall not promulgate any regulation” that—

- 3 (1) creates any unreasonable barriers to the ability of individuals
4 to obtain appropriate medical care;
- 5 (2) impedes timely access to health care services;
- 6 (3) interferes with communications regarding a full range of
7 treatment options between the patient and the provider;
- 8 (4) restricts the ability of health care providers to provide full
9 disclosure of all relevant information to patients making
10 health care decisions; [or]
- 11 (5) violates the principles of informed consent and the ethical
12 standards of health care professionals¹⁷

13 **C. Five Decades of Title X Regulations**

14 Since the 1970s, Title X regulations and guidance have governed grantees’
15 provision of a broad range of effective, medically approved contraception and
16 other family planning services, including nondirective pregnancy counseling and
17 referrals for out-of-program care, while ensuring compliance with section 1008.¹⁸
18 The sole exception was an anomalous 1988 “gag rule” that was swiftly enjoined
19 and never implemented in fact: it prohibited nondirective pregnancy counseling,
20 including referral for abortion, and for the first time required physical separation
21 of abortion care.¹⁹ The gag rule was upheld as a permissible construction of
22

17 42 U.S.C. § 18114.

18 *See* Compl. ¶¶ 29–47.

19 *Id.* ¶¶ 33–36; 53 Fed. Reg. 2922 (former 42 C.F.R. §§ 59.8, 59.9).

1 Title X in the pre-Nondirective Mandate case of *Rust v. Sullivan*, 500 U.S. 173
 2 (1991), but was rescinded in early 1993 amidst a public outcry and continued
 3 litigation.²⁰ Congress has since shut the door on regulations like the gag rule.

4 The Current Regulations reinstated the pre-*Rust* status quo.²¹ In 1996,
 5 Congress began including the Nondirective Mandate in its annual appropriations
 6 acts,²² prompting the HHS Secretary to observe in 2000 that “Congress has
 7 repeatedly indicated that it considers this requirement to be an important one[.]”²³
 8 The Secretary further noted that “the requirement for nondirective options
 9 counseling has existed in the Title X program for many years, and, with the
 10 exception of the period 1988–1992, it has always been considered to be a
 11 necessary and basic health service of Title X projects”; moreover, nondirective
 12 counseling is “consistent with the prevailing medical standards” recommended
 13 by national medical groups.²⁴ Accordingly, the Current Regulations require Title
 14 X projects to offer “neutral, factual information” about all pregnancy
 15 options—“prenatal care and delivery”; “infant care, foster care, and adoption”;

16
 17 ²⁰ *Id.* ¶¶ 37–39.

18 ²¹ 65 Fed. Reg. 41270 (Jul. 3, 2000), 42 C.F.R. Part 59; Compl. ¶¶ 40–47.

19 ²² Compl. ¶ 49 n.15.

20 ²³ 65 Fed. Reg. 41273.

21 ²⁴ *Id.*

1 and “termination of pregnancy”—and referral upon request, unless the patient
2 does not wish to receive such information about a particular option.²⁵

3 In addition, HHS’s [Program Requirements](#) require Title X projects to
4 provide nondirective pregnancy counseling, and incorporate the “QFP” and its
5 [updates](#).²⁶ The QFP reflects evidence-based best practices for “Providing Quality
6 Family Planning Services” in the United States, and requires that “[o]ptions
7 counseling should be provided” to pregnant patients as recommended by the
8 American College of Obstetricians and Gynecologists (ACOG) and others.²⁷

9 **D. The Final Rule**

10 The Final Rule²⁸ reverses longstanding policies reflected in the Current
11 Regulations and Program Requirements. It will disrupt Title X programs like
12 Washington’s that are currently functioning smoothly. If the Final Rule goes into
13

14 ²⁵ 42 C.F.R. § 59.5.

15 ²⁶ Beneski Decl. Ex. 2 (Program Requirements), 3 (QFP), 4 (QFP update).

16 ²⁷ QFP at 14; Coleman Decl. ¶¶ 63–64; Kost Decl. ¶¶ 22–25; AAP &
17 ACOG, *Guidelines for Perinatal Care* at 127 (7th ed. 2016) (patient with
18 unwanted pregnancy should be “fully informed in a balanced manner about all
19 options, including raising the child herself, placing the child for adoption, and
20 abortion”); [ACOG cmt.](#) at 6; Compl. ¶ 46.

21 ²⁸ 84 Fed. Reg. 7714, ECF No. 1-4 (Compl. Ex. A).

1 effect, it will impede patients’ access to complete and accurate information and
2 medical care, whether funded by Title X or otherwise—violating multiple
3 controlling statutes, irrationally overturning five decades of precedent, and
4 exceeding the scope of the Secretary’s rulemaking authority.

5 First, the Final Rule imposes coercive and misleading pregnancy
6 counseling requirements that brazenly violate the Nondirective Mandate and
7 other post-*Rust* laws. It broadly prohibits referrals for abortion, striking
8 requirements that patients be referred for out-of-program care upon request and
9 for “medically indicated” care.²⁹ It requires that all pregnant patients receive
10 directive referrals for prenatal care absent an “emergency,” regardless of the
11 patient’s wishes (or the provider’s medical judgment).³⁰ At the same time, the
12 Final Rule purports to permit “nondirective” pregnancy counseling (if provided
13 by physicians or “advanced practice providers”),³¹ but alternatively allows any
14 clinic staff to give only biased, one-sided information about carrying to term.³²
15

16
17 ²⁹ Final Rule §§ 59.5(a)(5), 59.5(b)(1), 59.14(a); *compare* current
18 42 C.F.R. §§ 59.5(a)(5), 59.5(b)(1); Compl. ¶¶ 71, 78.

19 ³⁰ Final Rule § 59.14(b); Compl. ¶ 72.

20 ³¹ Final Rule §§ 59.14(b)(1)(i), 59.2; Compl. ¶¶ 74–75.

21 ³² 84 Fed. Reg. 7714 (revised 42 C.F.R. § 59.14(b)); Compl. ¶ 72.
22

1 Second, the Final Rule imposes onerous and unworkable physical
2 separation requirements in addition to the statute’s financial separation
3 requirement, without sufficient justification. If a grantee or subgrantee provides
4 abortion care or referral, or engages in expressive or associational activities such
5 as supporting access to safe and legal abortion, those activities must be physically
6 separated from Title X services.³³ “Factors relevant to” adequate separation
7 include the existence of separate treatment, consultation, examination and
8 waiting rooms; separate office entrances and exits; separate phone numbers and
9 email addresses; separate websites; separate educational services; separate
10 personnel; separate workstations; separate electronic health records; and the
11 presence or absence of signage “referencing” abortion.³⁴ HHS emphasized that
12 employing separate Title X and non-Title X staff is insufficient separation, that
13 co-locating Title X activities and abortion-related activities within a single space
14 is impermissible, and that separate electronic health records systems are
15 mandatory.³⁵ Many clinics cannot bear the financial costs—which commenters
16 anticipate will be over twenty times HHS’s unsupported estimate of \$30,000 per
17
18

19 ³³ Final Rule § 59.15; *see id.* §§ 59.13, .14, .16; Compl. ¶ 90.

20 ³⁴ Final Rule § 59.15; Compl. ¶ 91.

21 ³⁵ Supp. Info., 84 Fed. Reg. at 7764–67, 7769.

22

1 clinic—or cannot meet the one-year deadline.³⁶ Those that try to scramble to
 2 comply will have to provide unethical and substandard care, divert limited
 3 resources away from caring for patients, and reduce their hours or close their
 4 doors during construction, further reducing access to care for no good reason.³⁷

5 Third, the Final Rule makes a number of other changes that will unlawfully
 6 and arbitrarily reduce access to care, impose needless costs, and undermine the
 7 purpose of Title X: removing the requirement that Title X services be “medically
 8 approved”;³⁸ requiring that Title X clinics offer or be in close proximity to
 9 “comprehensive primary health care services” (which are outside Title X’s
 10 scope);³⁹ jeopardizing the right to apply for a grant by vesting HHS with broad
 11 discretion to arbitrarily determine eligibility;⁴⁰ and limiting the uses of Title X
 12 funds (even uses expressly contemplated by the statute).⁴¹

13
 14 ³⁶ See [PPFA cmt.](#) at 32, 73–74; [NFPRHA cmt.](#) at 37; Eastlund Decl. ¶¶ 14–
 15 20 (estimating compliance costs of \$6.5 million in first year); 84 Fed. Reg. 7782.

16 ³⁷ Compl. ¶¶ 102–108; *see infra* at 15–16, 23–24, 34–35.

17 ³⁸ Compare Final Rule § 59.5(a)(1) with current 42 C.F.R. § 59.5(a)(1);
 18 Compl. ¶¶ 109–113.

19 ³⁹ Final Rule § 59.5(a)(12); Compl. ¶¶ 114–120.

20 ⁴⁰ Final Rule § 59.7(b); Compl. ¶¶ 126–132; [NFPRHA cmt.](#) at 31.

21 ⁴¹ Final Rule § 59.18(a); Compl. ¶¶ 133–134.

1 **E. The Final Rule’s Impact on Washington**

2 As Washington explained in its public comments, the unlawful Final Rule
 3 will disqualify critical Title X providers and dismantle the State’s successful
 4 family planning program.⁴² This will leave many patients with diminished or no
 5 access to needed care, exacerbating the negative health and economic outcomes
 6 Title X was meant to address.⁴³ The consequences for the State and its residents
 7 cannot be fully remedied if the Final Rule goes into effect.

8 Five current subrecipients of Title X grant funds operating 35 clinics in
 9 Washington have informed DOH that they cannot meet the Final Rule’s new
 10 requirements.⁴⁴ In 2017, these clinics served 89% of the Title X patients in
 11 Washington.⁴⁵ Their departure will leave 21 of Washington’s 39 counties without
 12 *any* Title X provider: 11 in Eastern Washington and 10 in Western Washington

13
 14
 15 _____
 16 ⁴² WA cmt. at 4–5, 24–25.

17 ⁴³ *Id.* at 26.

18 ⁴⁴ Harris Decl. ¶ 60. Other subrecipients, clinics, and individual providers
 19 are likely to leave as well, due to the Final Rule’s costly required separation and
 20 imposition of unethical and contraindicated medical care. *Id.* ¶ 64; *cf.* Eastlund
 21 Decl. ¶ 8; Kruse Decl. ¶ 40; Maisen Decl. ¶ 42; Adams Decl. ¶¶ 34–40, 43–51.

22 ⁴⁵ Harris Decl. ¶ 60.

1 (including six of the 10 most populous counties in the State).⁴⁶ Patients in those
 2 counties will have to travel hundreds of miles to the nearest Title X clinic,
 3 overburdening clinics that remain, while patients who cannot make the long trip
 4 or get into an overloaded clinic will lose access to services.⁴⁷ Patients in rural
 5 areas will suffer disproportionately, as they are more likely to be uninsured and
 6 underserved by health care providers generally.⁴⁸ Rural clinics are more likely to
 7 close entirely absent federal funding, exacerbating public health disparities
 8 among already underserved patients.⁴⁹ Students, too, will be especially impacted
 9 by the loss of Title X clinics near Washington colleges and universities,
 10 jeopardizing student health and educational attainment.⁵⁰ In the unlikely event
 11 that the remaining 11% of the network stays in place with no staff losses,⁵¹ these
 12 clinics cannot come close to filling the massive gap left by the departing

13
 14 ⁴⁶ Harris Decl. ¶ 61.

15 ⁴⁷ Harris Decl. ¶ 62.

16 ⁴⁸ Harris Decl. ¶¶ 65–66; [WA cmt.](#) at 23, 25; *see also* [AMA cmt.](#) at 4;
 17 [ACOG cmt.](#) at 11–12; [CA cmt.](#) at 13–14.

18 ⁴⁹ Harris Decl. ¶ 66; Eastlund Decl. ¶ 11; [WA cmt.](#) at 25.

19 ⁵⁰ Harris Decl. ¶¶ 67, 91; Eastlund Decl. ¶¶ 6–7; *see* [WA cmt.](#) at 3 & n.9;
 20 [NWLC cmt.](#) at 7 & n.22; [PPFA cmt.](#) at 95.

21 ⁵¹ *See supra* n.44.

22

1 subrecipients.⁵² For instance, Federally Qualified Health Centers (FQHCs) in
 2 Washington are structurally and financially unable to handle a massive influx of
 3 patients,⁵³ leaving many without care. HHS offered no evidence to support its
 4 “belie[f]” that new clinics able and willing to comply with the Final Rule will
 5 somehow rush in to immediately fill the massive gaps in the network.⁵⁴

6 The Final Rule’s drastic and harmful new requirements are not limited to
 7 clinics and their patients—they will also impact Washington’s ability to continue
 8 administering a Title X program at all. For instance, the separation provisions
 9 extend so far as to require DOH to *physically* separate its Olympia-based
 10 administration of Washington’s statewide Title X program from any State
 11

12 _____
 13 ⁵² Harris Decl. ¶ 68. Studies show that when specialized family planning
 14 clinics such as Planned Parenthood are excluded from statewide networks,
 15 patients lose access to care, and clinics that remain in the network are unable to
 16 fill the gaps even when the program is adequately funded. *See* [ACOG cmt.](#) at
 17 12-13; [APHA cmt.](#) at 4; [NFPRHA cmt.](#) at 34; [PPFA cmt.](#) at 16, 20; [GW Fac. cmt.](#)
 18 at 2–3; Beneski Decl. Ex. 5.

19 ⁵³ Marsalli Decl. ¶¶ 8–11; *see also* [ACOG cmt.](#) at 12; [Guttmacher cmt.](#) at
 20 14 & Table 2; [PPFA cmt.](#) at 16, 78.

21 ⁵⁴ Supp. Info., 84 Fed. Reg. 7766.
 22

1 activities related to abortion.⁵⁵ Even if Washington could continue its Title X
2 program despite this crippling burden, that program would receive less federal
3 funding due to network shrinkage as discussed above, and would offer
4 substandard care that would harm patients and increase costs in Washington.⁵⁶

5 If its Title X funds disappear entirely because of the Final Rule,
6 Washington's program will lose one third of its current funding. DOH would
7 suddenly have far less funding to allocate to family planning providers, resulting
8 in fewer patients receiving services and a more limited scope of services.⁵⁷ DOH
9 estimates that up to 72,000 Washingtonians would lose access to subsidized
10 family planning if this occurred.⁵⁸ The 16,000 Title X patients in Washington
11 who pay on a sliding scale may no longer be able to afford needed care if they
12 lose access to a Title X clinic and have to pay full price.⁵⁹ With fewer patients
13 being able to access the most effective forms of contraception, STI testing, cancer
14 screening, and other reproductive health care, the inevitable consequences will
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17 ⁵⁵ Harris Decl. ¶ 82; Maisen Decl. ¶¶ 26–37.

18 ⁵⁶ Harris Decl. ¶¶ 70–71, 84; *see infra* at 23–24, 32–34.

19 ⁵⁷ Harris Decl. ¶¶ 88–89, 94.

20 ⁵⁸ Harris Decl. ¶ 89.

21 ⁵⁹ Zerzan-Thul Decl. ¶ 18.

1 include more unintended pregnancies,⁶⁰ more maternal deaths,⁶¹ adverse
 2 maternal and pediatric health outcomes, undetected cancers, and other public
 3 health problems.⁶² Analyses show that nationally, every \$1 spent on family
 4 planning services results in over \$7 of cost savings⁶³—savings that will be
 5 slashed when the Final Rule impedes access to these services.

6 The State of Washington will bear increased public health costs. In 2017,
 7 Title X services saved the State multiple millions of dollars that otherwise would
 8 have been spent addressing preventable health issues; the costs imposed by the
 9 Final Rule will be well over \$100 million, and are projected at \$28 million in the
 10 first year alone if the rule is not enjoined.⁶⁴ The State’s Health Care Authority,
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12 ⁶⁰ See [WA cmt.](#) at 26; [AAN cmt.](#) at 3; [ACOG cmt.](#) at 2; [ACP cmt.](#) at 4;
 13 [APHA cmt.](#) at 5; [CA cmt.](#) at 4, 14, 16; [JIWH cmt.](#) at 1, 4–5; [NFPRHA cmt.](#) at 4,
 14 31–35; [PPFA cmt.](#) at 18, 80; [GW Fac. cmt.](#) at 7.

15 ⁶¹ Maternal mortality has been rising in the United States. [CA cmt.](#) at 13 &
 16 n.21; Beneski Decl. Ex. 6; Compl. ¶ 78 n.28.

17 ⁶² Harris Decl. ¶ 96; [WA cmt.](#) at 26; [PPFA cmt.](#) at 15–22, 33, 70, 80–81;
 18 [NFPRHA cmt.](#) at 31–35; [CA cmt.](#) at 4, 14; Compl. ¶¶ 159, 167–168.

19 ⁶³ Beneski Decl. Ex. 7; [WA cmt.](#) at 26; [ACOG cmt.](#) at 2; [Guttmacher cmt.](#)
 20 at 19; [NFPRHA cmt.](#) at 32; [PPFA cmt.](#) at 80.

21 ⁶⁴ [WA cmt.](#) at 5; Harris Decl. ¶ 95.
 22

1 which administers its Medicaid program (Apple Health) and other public health
 2 programs, currently funds nearly 50% of all births in Washington State, a figure
 3 likely to increase if unintended pregnancies rise due to the Final Rule.⁶⁵ Apple
 4 Health will pay for the care of many women who experience an unintended
 5 pregnancy after losing access to Title X services: currently, 81% of Title X clients
 6 are eligible for Apple Health or would become eligible in the event of a
 7 pregnancy; others may become eligible if a pregnancy affects their income by
 8 forcing them to stop working or reduce their hours, or by changing their family
 9 size.⁶⁶ Patients who are ineligible for Apple Health and who lose access to Title
 10 X services would turn to other parts of the safety net, or fall through the cracks.

11 Washington raised its serious concerns about network destruction in public
 12 comments on the proposed rule that preceded the Final Rule,⁶⁷ but HHS failed to
 13 address or even acknowledge Washington's unique concerns. Indeed, network
 14 destruction is part and parcel of the Trump Administration's goal in promulgating
 15 the Final Rule, which is to penalize clinics that provide abortion care *independent*
 16 of Title X.⁶⁸ HHS fundamentally fails to grapple with the real-world

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 18 ⁶⁵ Zerzan-Thul Decl. ¶ 15.

19 ⁶⁶ Zerzan-Thul Decl. ¶¶ 7, 13, 15, 19.

20 ⁶⁷ [WA cmt.](#) at 24 & Att. 1.

21 ⁶⁸ *See* Compl. ¶¶ 135–138.

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1 consequences of the Final Rule’s drastic and politically motivated changes.

2 **III. ARGUMENT**

3 **A. Legal Standard**

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

13 **B. Washington Is Likely To Succeed on the Merits of Its Administrative
14 Procedure Act Claims**

15 Washington is likely to succeed on the merits of its claims under the
16 Administrative Procedure Act (APA). The Final Rule should be “[held] unlawful
17 and set aside” because it is contrary to multiple controlling statutes, exceeds the
18 agency’s rulemaking authority, and is arbitrary and capricious. 5 U.S.C. § 706.

19 **1. The Final Rule is contrary to law**

20 Under the APA, courts must set aside agency action “in excess of statutory
21 jurisdiction, authority, or limitations” or otherwise “not in accordance with law.”
22

1 5 U.S.C. §§ 706(2)(A), (C). Where, as here, a plaintiff alleges that agency action
2 is contrary to law, courts apply the framework established in *Chevron, U.S.A.,*
3 *Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). *See Nw. Env'tl.*
4 *Advocates v. E.P.A.*, 537 F.3d 1006, 1014 (9th Cir. 2008). Under *Chevron*, the
5 court “must give effect to the unambiguously expressed intent of Congress.”
6 467 U.S. at 843. If “Congress has directly spoken to the precise question at issue”
7 and “the intent of Congress is clear, that is the end of the matter.” *Id.* at 842.
8 “If the statutory language is plain, [the court] must enforce it according to its
9 terms.” *King v. Burwell*, 135 S. Ct. 2480, 2489 (2015). Even where a statute
10 contains an ambiguity, no deference is owed to a *post hoc* agency interpretation
11 advanced for the first time in litigation, absent a formal rulemaking process.
12 *Price v. Stevedoring Serv. of Am., Inc.*, 697 F.3d 820, 830 (9th Cir. 2012).

13 The Final Rule violates *multiple* statutes plainly mandating (1) that Title X
14 pregnancy counseling be nondirective; (2) that HHS is forbidden to promulgate
15 any rule that creates barriers or impedes timely access to medical care, interferes
16 with patient–provider communications, or violates medical ethics or principles
17 of informed consent; and (3) that receipt of Title X services and information be
18 strictly “voluntary,” among other requirements of Title X’s text and purpose.

19 **a. The Final Rule violates the Nondirective Mandate**

20 Every year since 1996, Congress has included the Nondirective Mandate
21 in its appropriations acts. As to the amounts allocated for Fiscal Year 2019 “for
22

1 carrying out the program under title X of the PHS Act to provide for voluntary
2 family planning projects, . . . all pregnancy counseling shall be nondirective[.]”⁶⁹

3 The Final Rule defies Congress’s mandate by requiring that *all* pregnant
4 patients receive directive referrals for prenatal care—regardless of whether the
5 patient intends to continue the pregnancy, or whether the medical care provider
6 believes the referral is appropriate in light of the patient’s individual needs and
7 choices. Although section 59.14(b) pays lip service to the Nondirective Mandate
8 by purporting to permit “nondirective” counseling if a provider chooses to offer
9 it, the prenatal care referral requirement renders *any* counseling directive and
10 coercive because it pushes patients toward one option (carrying to term) and away
11 from another (abortion). Directing patients to the government’s preferred type of
12 medical care in response to a pregnancy cannot be reconciled with the
13 Nondirective Mandate. Even if pregnancy counseling that includes a mandatory
14 prenatal care referral could somehow be genuinely nondirective, the Final Rule
15 makes such counseling optional, as opposed to making it available to all patients
16 as required by the Nondirective Mandate. As alternatives to “nondirective”
17 counseling, the Final Rule lets providers instead choose to give pregnant patients
18 only politically biased “[i]nformation about maintaining the health of the mother

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⁶⁹ Pub. L. No. 115-245; Compl. ¶ 49.

1 and unborn child during pregnancy,”⁷⁰ and permits referrals to “social services
2 or adoption agencies” but not to abortion clinics. Final Rule § 59.14(b)(1).

3 These clear violations of the Nondirective Mandate render the Final Rule
4 invalid. *See E. Bay Sanctuary Covenant v. Trump*, 909 F.3d 1219, 1247 (9th Cir.
5 2018) (“an agency’s authority to promulgate categorical rules is limited by clear
6 congressional intent to the contrary”). HHS lacks the power to adopt regulations
7 that contradict the means (i.e., nondirective counseling) by which Congress
8 directed it to implement Title X. *See Waterkeeper Alliance v. E.P.A.*, 853 F.3d
9 527, 535 (D.C. Cir. 2017) (agencies and reviewing courts are “bound, not only
10 by the ultimate purposes Congress has selected, but by the means it has deemed
11 appropriate, and prescribed, for the pursuit of those purposes”) (quoting
12 *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994)). The coercive
13 counseling provisions (§§ 59.5), and the required separation of nondirective
14 counseling from Title X activities (§ 59.15), are unlawful statutory violations.

15 **b. The Final Rule violates section 1554 of the ACA**

16 Section 1554 of the ACA preserves the sanctity and integrity of the
17 patient–provider relationship by prohibiting interference by federal regulators. It
18 bars HHS from adopting “any” regulations, under Title X or otherwise, that

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20 ⁷⁰ “Unborn child” is a non-medical term signaling an ideological view of
21 reproductive health care. *See ACOG cmt.* at 4; *Guttmacher cmt.* at 7.

1 | impede patients’ access to medical information and quality care. 42 U.S.C. §
2 | 18114. HHS failed to even mention or consider these “clear” and “unambiguous”
3 | limitations on its authority, which cannot be reconciled with the Final Rule.
4 | *Chevron*, 467 U.S. at 842–43; *E. Bay Sanctuary Covenant*, 909 F.3d at 1247.

5 | The Final Rule “impedes timely access to care” and
6 | “creates . . . unreasonable barriers to the ability of individuals to obtain
7 | appropriate medical care” (§§ 18114(1), (2)) in a number of ways, including by
8 | imposing onerous, unworkable, and unnecessary physical separation
9 | requirements and mandating unethical practices that will disqualify and drive out
10 | the vast majority of current Title X providers in Washington, thereby reducing
11 | patients’ access to family planning services—especially in rural areas.⁷¹
12 | Requiring total physical separation of abortion care (and other newly prohibited
13 | activities like nondirective pregnancy counseling) is cost-prohibitive for many
14 | clinics and burdensome for patients.⁷² Those who live in one of the 21
15 | Washington counties that will lack a Title X provider because of the Final Rule
16 | will have to travel long distances to reach the nearest clinic, which may be
17 | impossible for some. Even for patients who are able to make the trip, the Final
18 | Rule impedes timely access by broadly prohibiting them from receiving referrals

19 | _____
20 | ⁷¹ *Supra* at 13–14.

21 | ⁷² *Supra* at 12, 14; [ACP cmt.](#) at 6; [CBD cmt.](#) at 2.

1 for abortion care (subject to an illusory exception that is meaningless in
 2 Washington),⁷³ leaving most patients to attempt to find a provider of the desired
 3 care on their own. Timely access is important because, while abortion is always
 4 safe (and “markedly safer than childbirth”), it is safest when performed early in
 5 a pregnancy.⁷⁴ The Final Rule further impedes access by artificially separating
 6 the provision of related health services,⁷⁵ and needlessly requiring clinics to
 7 divert resources from caring for patients to achieve separation.⁷⁶

8 The Final Rule “violates the principles of informed consent and the ethical
 9 standards of health care professionals” (§ 18114(5)) by requiring providers to
 10 withhold medically relevant information from their patients, coerce them into
 11 treatment that may be unwanted and unneeded, and knowingly depart from
 12 medical standards of care and fiduciary obligations to disclose information.⁷⁷ It

13
 14 ⁷³ There are no known primary care providers in Washington that offer
 15 abortion care. Harris Decl. ¶ 54; *see* Final Rule § 59.14(c)(2).

16 ⁷⁴ Compl. ¶ 77 & n.26; [Dr. Steinauer cmt.](#) at 2 & n.6.

17 ⁷⁵ [PPFA cmt.](#) at 33–34.

18 ⁷⁶ *Supra* at 12; Compl. ¶ 99; [PPFA cmt.](#) at 31–34.

19 ⁷⁷ HHS ignored numerous comments detailing the ethical standards for
 20 health care providers, including the central principle of informed consent. *See*,
 21 e.g., [WA cmt.](#) at 11 & nn.41–42; [AMA cmt.](#) at 3; [ACOG cmt.](#) at 1, 3–6; [NFPRHA](#)

1 also “interferes with communications regarding a full range of treatment options
 2 between the patient and the provider” and “restricts the ability of health care
 3 providers to provide full disclosure of all relevant information to patients making
 4 health care decisions” (§§ 18114(3), (4)) by requiring coercive counseling in
 5 violation of the Nondirective Mandate as described above.

6 **c. The Final Rule violates Title X’s text and purpose**

7 “In order to be valid regulations must be consistent with the statute under
 8 which they are promulgated.’ ” *E. Bay Sanctuary Covenant*, 909 F.3d at 1248
 9 (brackets omitted) (quoting *United States v. Larionoff*, 413 U.S. 864, 873 (1977)).
 10 Regulations “inconsistent with the statutory mandate or that frustrate the policy
 11 that Congress sought to implement” are invalid. *F.E.C. v. Democratic Senatorial*
 12 *Campaign Comm.*, 454 U.S. 27, 32 (1981).

13 Title X’s central purpose is to equalize access to comprehensive,
 14 evidence-based, voluntary family planning services. The combined effect of the
 15 unlawful aspects of the Final Rule—the separation requirements, coercive

16 _____
 17 [cmt.](#) at 6, 8–11, 21 & nn.43, 87–89; [Guttmacher cmt.](#) at 7–8 & nn.15–20; *id.* at
 18 12, 16; [PPFA cmt.](#) at 10–15 & nn.38–55; [ACP cmt.](#) at 5 & nn.3, 5, 9, 11; [ACNM](#)
 19 [cmt.](#) at 3 & n.6; [APHA cmt.](#) at 2–3; [CA cmt.](#) at 5–7; [JIWH cmt.](#) at 3; [Dr. Steinauer](#)
 20 [cmt.](#); [NIRH cmt.](#) at 3–4; *see* Compl. ¶¶ 81–84. *See also* Prager Decl. ¶¶ 16–25,
 21 32–33, 36, 42, 48; Madden Decl. ¶¶ 20–22, 35; Kruse Decl. ¶¶ 11–19, 30–31, 40.

1 counseling provisions, and others—will significantly *reduce* access to these
 2 services, frustrating the statute as a whole in service of HHS’s broad new
 3 interpretation of section 1008. This outcome “allow[s] the exception to swallow
 4 the rule, thereby undermining the purpose of the statute itself.” *Nat’l Fed’n of*
 5 *Fed. Emps. v. McDonald*, 128 F. Supp. 3d 159, 172 (D.D.C. 2015). These
 6 unethical and onerous provisions will drive out the vast majority (if not all) of
 7 Washington’s existing network of Title X clinics, and it will no longer be feasible
 8 for DOH to administer a Title X program while also performing other public
 9 health-related duties. As a result, Washington patients in need will lose access to
 10 family planning and related preventive health services, and others will receive a
 11 diminished level of care inconsistent with medical standards from clinics that
 12 may offer a sharply limited range of non-medically approved options.⁷⁸

13 The Final Rule violates individual statutory requirements as well,
 14 including Title X’s directive that the acceptance of family planning “services”
 15 and “information” “shall be voluntary[.]”⁷⁹ The “voluntary” requirement—
 16 referenced several times in the statute and in its title—forbids clinicians from
 17 providing patients with unwanted information or coercing them into unwanted
 18 medical treatment, but the Final Rule requires exactly that. In addition, the Final

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 20 ⁷⁸ See *infra* at 29–31.

21 ⁷⁹ 42 U.S.C. § 300a-5; see also *id.* § 300(a).

1 Rule inexplicably limits the use of Title X funds for core functions such as “bulk
2 purchasing of contraceptives,” “clinical training for staff,” and “community
3 outreach,” including development and distribution of “educational materials.”⁸⁰
4 Title X expressly contemplates that funds should be used to “offer . . . effective
5 family planning methods” and “develop[] and mak[e] available family planning
6 . . . information (including educational materials).”⁸¹

7 These numerous statutory violations on their own are more than enough to
8 establish Washington’s likelihood of success on the merits at this stage.

9 **2. The Final Rule is arbitrary and capricious**

10 In addition to violating multiple statutes, the Final Rule is arbitrary and
11 capricious. Its harmful new requirements further an improper goal: to shift TitleX
12 away from its original bipartisan vision of equalizing access to modern, effective
13 contraception, and toward policy preferences ungrounded in law or public health.
14 In pursuit of this goal, HHS overhauled decades of Title X regulations while
15 ignoring and brushing aside its own precedent, its evidence-backed Program
16 Requirements, and the extensive public comments opposing the rule. HHS made
17 no serious effort to balance these real-world problems against the speculative and
18 baseless “risks” of improper commingling and public misperception it used to

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20 ⁸⁰ Final Rule § 59.18; Supp. Info., 84 Fed. Reg. 7774.

21 ⁸¹ 42 U.S.C. §§ 300(a), 300a-3(a).

1 justify the sweeping changes. Its rationales for various aspects of the Final Rule
2 are illogical, unsupported, and contrary to the evidence in the “whole”
3 administrative record. *See* 5 U.S.C § 706.

4 Courts must set aside agency action that is “arbitrary, capricious, an abuse
5 of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2). To
6 survive judicial review, the agency action must be based on a “reasoned analysis”
7 that indicates the agency “examine[d] the relevant data and articulate[d] a
8 satisfactory explanation for its action including a rational connection between the
9 facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of U.S. v. State*
10 *Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42–43 (1983) (citation and internal
11 quotation marks omitted). When an agency reverses position, it must “supply a
12 reasoned analysis for the change,” *id.* at 42, and may not “depart from a prior
13 policy *sub silentio* or simply disregard rules that are still on the books,”
14 *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Further, any
15 “serious reliance interests must be taken into account,” *id.*, particularly where
16 “decades of . . . reliance on the Department’s prior policy” demand a fulsome
17 explanation for the reversal. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117,
18 2126 (2016). In general, a rule is arbitrary and capricious where the agency
19 “relied on factors which Congress has not intended it to consider, entirely failed
20 to consider an important aspect of the problem, offered an explanation for its
21 decision that runs counter to the evidence before the agency, or is so implausible
22

1 that it could not be ascribed to a difference in view or the product of agency
 2 expertise.” *State Farm*, 463 U.S. at 43. “[A]gency action is lawful only if it rests
 3 ‘on a consideration of the relevant factors,’ ” *Michigan v. EPA*, 135 S.Ct. 2699,
 4 2707 (2015) (quoting *State Farm*, 463 U.S. at 43), and the agency must consider
 5 “the advantages *and* the disadvantages” of the proposal before taking action, *id.*
 6 HHS’s Final Rule is arbitrary and capricious for a host of reasons.

7 **a. Failure to consider medical ethics and patient-focused care**

8 HHS failed to justify the Final Rule’s interference in the patient–provider
 9 relationship, which needlessly endangers patients’ health and undermines their
 10 trust in the health care system. *Cf. Nat’l Inst. of Family & Life Advocates v.*
 11 *Becerra*, 138 S.Ct. 2361, 2374 (2018) (“[T]his Court has stressed the danger of
 12 content-based regulations in the fields of medicine and public health, where
 13 information can save lives.”) (citation and internal quotation marks omitted).
 14 “High-quality health care is founded on complete, accurate, and unbiased
 15 information and relies on a relationship of trust between a patient and their health
 16 care professional.”⁸² Impacts on the “ethical standards of health care
 17 professionals” and “principles of informed consent” are important factors that
 18 Congress directed HHS to consider as part of *any* rulemaking. 42 U.S.C.
 19 § 18114(5). Yet the agency completely disregarded extensive and unanimous
 20

21 ⁸² [AAN cmt.](#) at 4; *see also supra* n.77.

1 public comments from leading medical associations, public health policy
2 organizations, medical and infrastructure experts, and states (including
3 Washington) pointing out that the coercive and misleading counseling provisions
4 create serious ethical and legal problems for physicians, nurses, and other
5 clinicians.⁸³ HHS barely acknowledged these concerns, and failed to respond
6 directly to a single one of the specific ethical problems raised by commenters.⁸⁴

7 A primary justification for the unethical counseling requirements is that
8 HHS wanted to expand eligibility for Title X funds to “diverse” providers who
9 are no longer obligated to offer “medically approved” contraceptive methods and
10 who object to nondirective counseling, including referral for abortion.⁸⁵ This
11 justification is irrationally overbroad,⁸⁶ and there is no indication that Congress
12 wanted HHS to prioritize the interests of an unknown minority of health care
13 providers over the needs of the patients whom Title X was intended to help (and
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15
16 ⁸³ *See supra* n.77.

17 ⁸⁴ *See* Supp. Info., 84 Fed. Reg. 7748 (HHS “does not believe” the Final
18 Rule violates ethical requirements, offering no supporting analysis or evidence).

19 ⁸⁵ *Id.* at 7716–17, 7719, 7746–47; *see supra* n.38.

20 ⁸⁶ *See* Compl. ¶ 86; *see also, e.g., PPF A cmt.* at 8 (conscience laws are not
21 “a sword to be wielded against all *other* providers”).
22

1 the ethical obligations of all medical care providers).⁸⁷ Prioritizing “conscience”
 2 objectors, while simultaneously excluding experienced clinics with a
 3 demonstrated ability to provide a full range of FDA-approved options,
 4 undermines Title X’s requirement that projects offer a “broad range” of
 5 “effective” family planning methods and services.⁸⁸ Even if HHS’s “conscience”
 6 rationale had some legitimacy (which it does not), the agency cannot rely on it
 7 exclusively while disregarding several “important aspect[s] of the problem”
 8 Congress expressly identified. *State Farm*, 463 U.S. at 42–43, 55.

9 HHS fails to offer any rational justification whatsoever for the Final Rule’s
 10 other intrusions into the patient–provider relationship. It fails to explain why
 11 “medically indicated” abortion referrals are no longer permitted (*see*
 12 § 59.5(b)(1)), or to justify putting patients in danger by withholding referrals and
 13 delaying access to care (§§ 59.5(a)(5), .14);⁸⁹ fails to explain why the Final Rule
 14 does not permit qualified nurses and trained staff to provide “nondirective”
 15 pregnancy counseling (although any Title X staff are permitted to provide
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 18 ⁸⁷ *See* Compl. ¶ 86.

19 ⁸⁸ 42 U.S.C. § 300(a).

20 ⁸⁹ *Supra* n.29; *see* Compl. ¶¶ 77–80; [PPFA cmt.](#) at 92; [ACOG cmt.](#) at 5–6;
 21 [AMA cmt.](#) at 3; [CA cmt.](#) at 16; [Guttmacher cmt.](#) at 8; [Dr. Steinauer cmt.](#) at 2.

1 directive counseling) (§§ 59.2, .14(b)(1));⁹⁰ and tries to rationalize the coercive,
 2 directive, and demeaning requirement that all pregnant patients be given prenatal
 3 care referrals (§ 59.14(b)(1)) on the irrelevant grounds that prenatal care is
 4 deemed “medically necessary” for purposes of Medicaid reimbursement—which
 5 has no bearing on whether such care is appropriate for all patients.⁹¹

6 **b. Disregarding program requirements and standards of care**

7 In its drive to remake the Title X program as a vehicle for the
 8 Administration’s unrelated policy goals, HHS also ignored its own Program
 9 Requirements—including the QFP, which was prepared by HHS’s sub-agencies
 10 in 2014, backed by extensive research, and fully reaffirmed in December 2017.

11 The Final Rule contradicts standards of care, including those reflected in
 12 the QFP, in a number of ways: by mandating coercive and directive pregnancy
 13 counseling (§ 59.5, .14); permitting providers to offer limited, non-medically-
 14 approved family planning options (*see* § 59.5(a)(1)); prohibiting referrals for
 15 abortion absent a medical “emergency” (§ 59.14(b));⁹² and requiring separate sets

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 17 ⁹⁰ Compl. ¶ 75.

18 ⁹¹ Zerzan-Thul Decl. ¶ 11 (prenatal care is not appropriate if a pregnancy
 19 will be terminated); Kimelman Decl. ¶¶ 9–10 (same); *see* 84 Fed. Reg. 7762.

20 ⁹² This restriction also exceeds HHS’s rulemaking authority to the extent
 21 it regulates referrals for abortion that are needed to protect the patient’s life,
 22

1 of medical records for any patients who receive abortion care or counseling
 2 (§ 59.15). Contrary to these provisions, the QFP requires “client-centered” care,
 3 which for pregnant patients includes nondirective “[o]ptions counseling” with
 4 “appropriate referrals,” consistent with ACOG standards; if “pregnancy
 5 abnormalities or problems are suspected,” the QFP requires treatment or
 6 appropriate referral, *regardless* of whether there is an “emergency.”⁹³ The QFP
 7 emphasizes that clinics should offer a “full range of FDA-approved contraceptive
 8 methods,”⁹⁴ and stresses the importance of consistent electronic health records to
 9 ensure accuracy and improve patients’ health.⁹⁵

10 The Final Rule’s heedless departures from these prevailing standards put
 11 patients’ lives and health at risk. Requiring separate records is not only extremely
 12 costly⁹⁶—it increases the likelihood of medical error, posing a “considerable
 13 _____
 14 health, or safety, including in cases of rape or incest, which are outside Title X’s
 15 scope. *See* 42 U.S.C. § 300a-6; *see* Compl. ¶ 78 & n.27.

16 ⁹³ QFP (Beneski Decl. Ex. 3) at 2, 4, 13–14.

17 ⁹⁴ *Id.* at 2, 7, 10 (Fig. 3), 11, 24, 39.

18 ⁹⁵ *Id.* at 22, 24; *see also* 42 U.S.C. § 300jj-11 (emphasizing importance of
 19 integrated electronic health records and establishing federal standards re same).

20 ⁹⁶ NFPRHA cmt. at 36–37 (changing *one* electronic template could cost
 21 \$30,000 per clinic—a fraction of the cost of creating a separate new system).
 22

1 health risk to patients.”⁹⁷ Failing to refer patients for needed care and impeding
 2 their ability to choose effective, FDA-approved contraceptives predictably harms
 3 their health and well-being,⁹⁸ and in the long run, will undermine trust in the
 4 medical care system, worsening health outcomes overall.⁹⁹ HHS fails to “supply
 5 a reasoned analysis” for departing from the QFP. *State Farm*, 463 U.S. at 42.
 6 Indeed, it fails to even *acknowledge* the QFP, reversing it *sub silentio*. See *Fox*
 7 *Television Stations*, 556 U.S. at 515; see also *Lone Mountain Processing, Inc. v.*
 8 *Sec’y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013) (agency must show that
 9 prior policies are not being “casually ignored”). HHS quietly ignored the QFP for
 10 good reason: it cannot rationally justify requirements that fly in the face of
 11 evidence-backed medical standards and principles of patient-centered care.

12 **c. Network destruction and unnecessary burdens**

13 The Final Rule’s unworkable and unnecessary physical separation
 14 requirements, along with its invasion of the patient–provider relationship to
 15 mandate unethical medical care, will force out the subrecipients and clinics

18 ⁹⁷ [PPFA cmt.](#) at 34 & n.135; [WA cmt.](#) at 24; Compl. ¶ 104.

19 ⁹⁸ *Supra* at 16–17.

20 ⁹⁹ See [AMA cmt.](#) at 2; [ACOG cmt.](#) at 3; [PPFA cmt.](#) at 11 & n.42; [NFPRHA](#)
 21 [cmt.](#) at 4, 10, 21–24; [ACNM cmt.](#) at 3.

1 comprising the vast majority of Washington’s Title X network.¹⁰⁰ Any remaining
 2 clinics will be excessively burdened by the *ultra vires* “comprehensive primary
 3 health care” requirement (§ 59.5(a)(12));¹⁰¹ the new limitations on the use of
 4 grant funds (§ 59.18);¹⁰² and the vagueness of the separation “factors,” which
 5 increase uncertainty and the cost of compliance—particularly since the Final
 6 Rule establishes an initial grant eligibility hurdle (§ 59.7(b)) that gives HHS
 7 considerable discretion to arbitrarily reject applications prior to merits review.¹⁰³

8 Washington explained in its public comments that these burdensome
 9 requirements will leave over half its counties without a Title X provider, with the
 10 devastating effects falling “particularly hard on uninsured patients and those in
 11 rural areas, who in some cases will have no other reasonable option for obtaining

12 _____
 13 ¹⁰⁰ *Supra* at 13–14, 23–24.

14 ¹⁰¹ Requiring family planning clinics to provide primary care or be in
 15 “close proximity” to a referral source is costly and will disqualify clinics located
 16 in already-underserved areas. Compl. ¶¶ 119–120; [WA cmt.](#) at 20; [AMA cmt.](#) at
 17 4; [ACOG cmt.](#) at 13; [ACP cmt.](#) at 8–9; [PPFA cmt.](#) at 70. Moreover, it exceeds
 18 HHS’s rulemaking authority, since Title X pertains exclusively to “family
 19 planning” services, not primary care. *See generally* 42 U.S.C. § 300 *et seq.*

20 ¹⁰² *See supra* at 26–27 & n.80.

21 ¹⁰³ Compl. ¶¶ 126–129; [NFPRHA cmt.](#) at 14; [PPFA cmt.](#) at 31.

1 family planning services.”¹⁰⁴ Lack of access to Title X services will worsen
 2 public health outcomes—and increase costs to the State—because the number of
 3 unintended pregnancies will rise, more STIs and cancers will go undetected and
 4 untreated, and more people will become eligible for (and in need of) safety-net
 5 care.¹⁰⁵ Title X preventive care saves millions of dollars a year in health care
 6 costs.¹⁰⁶ Yet in promulgating the Final Rule, HHS turned a deaf ear to the
 7 concerns of Washington and other grantees; the agency simply asserted, with no
 8 evidence, that it “does not believe” the Final Rule will have *any* impact on
 9 patients’ access to care.¹⁰⁷ In baselessly claiming that patients will be unaffected,

11 ¹⁰⁴ [WA cmt.](#) at 23–26 & Att. 1; *see also* [Gutmacher cmt.](#) at 9 (separation
 12 requirements will “effectively exclude” clinics that offer abortion or are affiliated
 13 with clinics that do so); Compl. ¶¶ 87–89, 93, 99, 139–153.

14 ¹⁰⁵ *See* [WA cmt.](#) at 23–27 (rule will “reduce access to essential preventive
 15 health services” and “impose tens of millions of dollars of costs” on state
 16 treasuries); [NFPRHA cmt.](#) at 31–35 (lack of access due to Final Rule is “likely
 17 to lead to a significant public health crisis”); [PPFA cmt.](#) at 15–22 (extensively
 18 discussing “gaps in access to care, harm [to] population health,” and “significant,
 19 unnecessary costs” the rule will cause); *see supra* at 16–18.

20 ¹⁰⁶ Beneski Decl. Ex. 7.

21 ¹⁰⁷ Supp. Info., 84 Fed. Reg. 7725; *see also id.* at 7766, 7775, 7785.

1 HHS also implied that complete physical separation would somehow be simple
 2 and cheap: it wildly underestimated the costs and burdens without backing up its
 3 lowball “estimate”¹⁰⁸ or justifying its rejection of substantiated cost assessments
 4 submitted in public comments.¹⁰⁹

5 The Final Rule’s destruction of existing, effective family planning
 6 networks, and the resulting loss of access to much-needed care, is another
 7 “important aspect of the problem” that HHS failed to confront or address. Title
 8 X’s concerns with serving high numbers of patients and adequately addressing
 9 local needs, *see* 42 U.S.C. § 300(b), and its stated purpose of making
 10 “comprehensive” services “readily available to all,” Pub. L. No. 91-572, § 2,
 11

12 ¹⁰⁸ *See id.* at 7718, 7782 (estimating costs at \$30,000 per clinic and \$36
 13 million nationwide, citing no evidence); *id.* at 7781 (asserting that moving
 14 abortion care and referral to “distinct facilities” “likely entails only minor costs”).

15 ¹⁰⁹ *See* [PPFA cmt.](#) at 31–33 (cost estimates of \$.5 to \$1.5 million;
 16 duplicating operations would further increase costs by 50–100%); [Prof. Brown](#)
 17 [cmt.](#) (HHS’s cost estimate is “completely unrealistic”); [NFPRHA cmt.](#) at 36–37
 18 (costs will be “orders of magnitude more” than HHS’s estimate); [MO FHC cmt.](#)
 19 at 8 (locating and opening health facilities “costs hundreds of thousands, or even
 20 millions, of dollars”); [WA cmt.](#) at 23; [ACP cmt.](#) at 6; [APHA cmt.](#) at 6; [CBD cmt.](#)
 21 at 2; Compl. ¶¶ 87–89 & n.32, 97–100; *see also* Eastlund Decl. ¶¶ 14–20.
 22

1 show that network adequacy and access to care are critical, central issues.
 2 Congress also expressly identified “timely access” and “barriers” to medical care
 3 as issues HHS must account for as part of *any* rulemaking. 42 U.S.C.
 4 §§ 18114(1), (2). HHS offered no evidence that its concerns about “potential”
 5 commingling or a “risk” of confusion are anything more than speculative¹¹⁰ and
 6 failed to respond to comments regarding the adequate and “thorough” monitoring
 7 and compliance systems already in place.¹¹¹ Even assuming HHS’s unfounded
 8 concerns have *some* relevance, the agency cannot rely on them exclusively while
 9 completely ignoring factors that Congress actually deemed important.

10 **d. Failing to consider reliance interests**

11 The Final Rule ignores and undermines reliance interests developed during
 12 five decades of Title X regulation. *See Fox Television Stations*, 556 U.S. at 515
 13 (2009). Washington has for decades relied on being able to administer its family
 14 planning program without having to physically separate its work on other State
 15 _____

16 ¹¹⁰ In fact, HHS admits that “demonstrated abuses of Medicaid funds do
 17 not necessarily mean that Title X grants are being abused . . .” Supp. Info.,
 18 84 Fed. Reg. 7725. And HHS fails to explain why these “risks” justify physical
 19 separation of abortion care, but not other out-of-program care that a Title X clinic
 20 may provide (such as prenatal care). *See* Compl. ¶ 102.

21 ¹¹¹ [WA cmt.](#) at 16–18; [CA cmt.](#) at 19–20; *see* Harris Decl. ¶¶ 41–49.

1 business.¹¹² Providers and clinics rely on being able to provide Title X services
 2 without violating their professional responsibilities, and patients expect providers
 3 to act ethically and fulfill their fiduciary duties regardless of who funds their
 4 services.¹¹³ Patients also rely on being able to obtain comprehensive reproductive
 5 health services from specialized clinics,¹¹⁴ whether federally funded or not—but
 6 an abrupt loss of funding will force at least some current Title X clinics to close
 7 or reduce their services, leaving vulnerable patients without access to what may
 8 be their only source of care.¹¹⁵ Simply brushing aside these “decades
 9 of . . . reliance on the Department’s prior policy” without adequate justification,
 10 as HHS has done, is unacceptable under the APA. *Encino Motorcars*, 136 S. Ct.
 11 at 2126.

12 **C. Washington Will Suffer Irreparable Harm Absent Preliminary Relief**

13 The harm analysis “focuses on irreparability, irrespective of the magnitude
 14 of the injury.” *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (internal
 15 quotation marks omitted). Washington is irreparably harmed in at least three
 16

17 ¹¹² Harris Decl. ¶ 11; *see* Compl. ¶¶ 107, 141; *supra* at 15–16.

18 ¹¹³ Maisen Decl. ¶¶ 20, 40–42; Kruse Decl, ¶¶ 2, 17–32, 38–39;
 19 Eastlund Decl. ¶ 8; *see* Compl. ¶¶ 81, 141.

20 ¹¹⁴ Compl. ¶ 56 & n.22.

21 ¹¹⁵ *Supra* at 13–15.

1 ways. The Final Rule is likely to (1) seriously disrupt or destroy Washington’s
 2 existing Title X network, (2) impose uncompensable financial costs on the State,
 3 and (3) harm the health and well-being of Washington patients and providers.¹¹⁶

4 First, Washington will be harmed because the Final Rule will destroy its
 5 family planning network, forcing out subrecipients and clinics that served almost
 6 90% of Title X patients in 2017.¹¹⁷ Federal action that undermines a state program
 7 and impedes its purpose constitutes irreparable harm. “An organization is harmed
 8 if the actions taken by [the defendant] have ‘perceptibly impaired’ the
 9 [organization’s] programs.” *League of Women Voters of U.S. v. Newby*, 838 F.3d
 10 1, 8 (D.C. Cir. 2016) (internal quotation marks and citation omitted); *see also*
 11 *Fair Emp’t Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268,
 12 1276 (D.C. Cir. 1994) (anti-discrimination organization was injured because
 13 defendant’s “discriminatory actions . . . interfered with [plaintiff’s] efforts and
 14 programs and . . . also required [it] to expend resources to counteract” the
 15 discrimination); *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1029 (9th Cir. 2013)
 16 (“ongoing harms to [plaintiffs’] organizational missions” established likelihood
 17 of irreparable harm); *E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094,

18 _____
 19 ¹¹⁶ “That [Washington] promptly filed an action following the issuance of
 20 the [Final Rule] also weighs in [its] favor” for the irreparable harm analysis. *Id.*

21 ¹¹⁷ *Supra* at 13–16.
 22

1 1116 (N.D. Cal. 2018) (“the Organizations ‘have established a likelihood of
2 irreparable harm’ based on their showing of serious ‘ongoing harms to their
3 organizational missions,’ including diversion of resources and the non-
4 speculative loss of substantial funding from other sources”) (quoting *Whiting*,
5 732 F.3d at 1029).¹¹⁸ Based on the extensive evidence of network destruction
6 discussed above, Washington satisfies this standard. Given the imminent loss of
7 almost 90% of Washington’s Title X network because of the Final Rule, “the
8 only serious disagreement is not whether [Washington] will be harmed, but *how*
9 *much.*” *Pennsylvania v. Trump*, 351 F. Supp. 3d 791, 828 (E.D. Pa. 2019).

10 Second, the Final Rule will harm Washington economically, and there is
11 no mechanism by which Washington could recover damages from the United
12

13 ¹¹⁸ Courts routinely find a likelihood of irreparable harm in similar
14 scenarios involving likely clinic closures, staff layoffs, and loss of access to
15 health care services. *See, e.g., Planned Parenthood of Ind., Inc. v. Comm’r of Ind.*
16 *State Dep’t Health*, 699 F.3d 962, 980–81 (7th Cir. 2012); *W. Ala. Women’s Ctr.*
17 *v. Williamson*, 120 F. Supp. 3d 1296, 1317–20 (M.D. Ala. 2015); *Jackson*
18 *Women’s Health Org. v. Currier*, 940 F. Supp. 2d 416, 423–24 (S.D. Miss. 2013);
19 *N.Y. State Nat’l Org. for Women v. Terry*, 886 F.2d 1339, 1362 (2d Cir. 1989)
20 (“Those women denied access cannot be compensated by money damages;
21 injunctive relief alone can assure them the clinics’ availability.”).

1 States. Uncompensable economic harm, such as that caused by unlawful federal
 2 agency action, satisfies the irreparable harm standard. *Azar*, 911 F.3d at 581.¹¹⁹
 3 The first component of Washington’s economic harm is the loss of granted Title
 4 X funds—up to \$4 million—that would follow the dramatic contraction of its
 5 network.¹²⁰ The second component is increased costs to the State of providing
 6 family planning services to patients who lose access to Title X clinics, since the
 7 income eligibility criteria for state-funded family planning services overlap with
 8 the Title X criteria.¹²¹ *See Azar*, 911 F.3d at 572 (economic injury to states was
 9 “reasonably probable” where agency rule would increase reliance on state-funded
 10 programs). The third component is increased costs to Apple Health and other
 11 state programs due to a rise in unintended pregnancies and other health
 12 consequences caused by the Final Rule. *See Pennsylvania*, 351 F. Supp. 3d at
 13 827 (finding irreparable harm where states would “become obligated to shoulder

14
 15 ¹¹⁹ *See also Idaho v. Coeur d’Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir.
 16 2015); *Texas v. United States*, 809 F.3d 134, 186 (5th Cir. 2015); *Pennsylvania*,
 17 351 F. Supp. 3d at 828; *California v. Health & Human Servs.*, 351 F. Supp. 3d
 18 1267, 1297 (N.D. Cal. 2019).

19 ¹²⁰ *Supra* at 16; Harris Decl. ¶ 70 (if it lost most of its network, DOH
 20 “would not continue to receive the roughly \$4 million current award from HHS”).

21 ¹²¹ Harris Decl. ¶ 12; Zerzan-Thul Decl. ¶¶ 7, 10, 19.

1 much of the burden of providing contraceptive services to women who lose
 2 contraceptive care” as a result of agency rules). Here, “[a]s a direct result of
 3 HHS’s new rule, millions of unnecessary dollars will be spent in Washington to
 4 pay for unintended pregnancies, unplanned births, abortions, treatment of
 5 sexually transmitted infections, cervical and breast cancer treatment, and other
 6 public health risks that the Title X program is designed to prevent.”¹²²

7 Third, thousands of Washington residents will be seriously harmed by the
 8 Final Rule. Injury to residents’ health and well-being irreparably harms the State
 9 itself. *See Pennsylvania*, 351 F. Supp. 3d at 828 (“the States also stand to suffer
 10 injury to their interest in protecting the safety and well-being of their citizens”);
 11 *California v. Health & Human Servs.*, 281 F. Supp. 3d 806, 830 (N.D. Cal. 2017),
 12 *aff’d in pertinent part sub nom. California v. Azar*, 911 F.3d 558 (9th Cir. 2018)
 13 (finding irreparable injury based in part on “what is at stake: the health of
 14 Plaintiffs’ citizens and Plaintiffs’ fiscal interests”). The Final Rule will harm
 15 Washington residents’ health by reducing both access to services and quality of
 16 services. Some current Title X patients will lose access to family planning
 17 services entirely,¹²³ especially in rural areas, putting their lives and health at

18
 19 ¹²² Zerzan-Thul Decl. ¶ 22; *see also id.* ¶¶ 13, 15, 19; *supra* nn.60–62.

20 ¹²³ Harris Decl. ¶¶ 59 (“thousands of people in Washington” will lose
 21 access), 62, 65–67, 83, 86, 88–89 (“reduction is guaranteed”), 90 (quantifying
 22

1 risk.¹²⁴ Patients who can still access Title X services will be harmed because the
 2 Final Rule’s unethical and misleading counseling requirements, combined with
 3 total physical separation from counseling and care to which patients cannot be
 4 referred, will impede patients’ ability to obtain the care they want and need and
 5 coerce them into receiving unwanted or medically inappropriate treatment.

6 **D. Equity and the Public Interest Strongly Favor an Injunction**

7 When the government is a party, the final two *Winter* factors merge.
 8 *Drakes Bay Oyster Co. v. Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). The
 9 balance of the equities and public interest strongly favor an injunction. “[T]he
 10 purpose of such interim equitable relief is not to conclusively determine the rights
 11 of the parties, but to balance the equities as the litigation moves forward.” *Trump*
 12 *v. Int’l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017). “There is
 13 generally no public interest in the perpetuation of unlawful agency action. To the
 14 contrary, there is a substantial public interest in having governmental agencies
 15 abide by the federal laws that govern their existence and operations.” *League of*

16 _____
 17 residents who would lose services), 91–94; Zerzan-Thul Decl. ¶¶ 10, 21.

18 ¹²⁴ Harris Decl. ¶ 97 (“As a result of the Final Rule, more unplanned
 19 pregnancies and unwanted childbearing will occur, cervical cancers will not be
 20 diagnosed in early stages when they are treatable, and poor health outcomes will
 21 result from undiagnosed and untreated STIs”); Zerzan-Thul Decl. ¶¶ 12–13.

1 *Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (citations and
2 internal quotation marks omitted). As discussed above, the Final Rule is unlawful
3 for numerous reasons and will wreak havoc on a successful and beneficial
4 program. Preserving the status quo will not harm Defendants, and refraining from
5 enforcing the Final Rule will cost them nothing. *See Diaz v. Brewer*, 656 F.3d
6 1008, 1015 (9th Cir. 2011) (court may waive Rule 65(c) bond requirement).

7 **E. Relief Requested**

8 For all the reasons above, the State of Washington requests that the Final
9 Rule be preliminarily enjoined in full. *See, e.g., Regents of the Univ. of Cal. v.*
10 *U.S. Dep't of Homeland Sec.*, 908 F.3d 476, 511–12 (9th Cir. 2018); *City of Los*
11 *Angeles v. Sessions*, 293 F. Supp. 3d 1087, 1100–01 (C.D. Cal. 2018) (enjoining
12 rule nationwide to ensure “even playing field” in competition for federal grants).
13 Alternatively, and pursuant to the same standard, the State requests that the Court
14 stay the rule’s effective date during the pendency of this litigation pursuant to
15 5 U.S.C. § 705. *Cf. Bauer v. DeVos*, 325 F. Supp. 3d 74, 104–05 (D.D.C. 2018).
16 The State requests a ruling prior to the effective date of 12:00 a.m. on
17 May 3, 2019.

18 **IV. CONCLUSION**

19 For all the reasons above, the State of Washington requests that the Court
20 preliminarily enjoin Defendants from implementing or enforcing the Final Rule.
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DATED this 22nd day of March, 2019.

ROBERT W. FERGUSON
Attorney General

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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 22nd day of March, 2019, at Seattle, Washington.

/s/ Jeffrey T. Sprung
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7 **UNITED STATES DISTRICT COURT**
8 **EASTERN DISTRICT OF WASHINGTON**
AT YAKIMA

9 STATE OF WASHINGTON,

10 Plaintiff,

11 v.

12 ALEX M. AZAR II, et al.,

13 Defendants.
14

NO. 1:19-cv-3040-SAB

ORDER GRANTING STATE OF
WASHINGTON'S MOTION FOR
PRELIMINARY INJUNCTION

[PROPOSED]

NOTED FOR: April 25, 2019
With Oral Argument at 10:00 a.m.

15 NATIONAL FAMILY PLANNING
& REPRODUCTIVE HEALTH
16 ASSOCIATION, et al.,

17 Plaintiffs,

18 v.

19 ALEX M. AZAR II, et al.,

20 Defendants.
21
22

1 This matter came before the Court on State of Washington's Motion for
2 Preliminary Injunction. The Court has considered all of the following:

- 3 1. State of Washington's Motion for Preliminary Injunction (ECF
4 No. _____) with supporting declarations and exhibits;
- 5 2. Defendants' Response to State of Washington's Motion for
6 Preliminary Injunction (ECF No. _____);
- 7 3. State of Washington's s Reply in Support of Motion for Preliminary
8 Injunction (ECF No. _____); and
- 9 4. The entire record in the above-captioned matter.

10 Being fully apprised of the matter, now, therefore, it is hereby

11 ORDERED, ADJUDGED, AND DECREED that State of Washington's
12 Motion for Preliminary Injunction is hereby GRANTED.

13 The Court finds that the State of Washington has established a likelihood
14 of success on the merits of its claims under the Administrative Procedure Act,
15 that it would suffer irreparable harm absent preliminary injunctive relief, and that
16 the balance of equities and the public interest weigh in favor of an injunction.

17 Defendants and their officers, agents, servants, employees, and attorneys,
18 and any person in active concert or participation with them, are ENJOINED from
19 implementing or enforcing the Final Rule entitled *Compliance With Statutory*
20 *Program Integrity Requirements*, 84 Fed. Reg. 7714 (March 4, 2019), in any
21 manner or in any respect, and shall preserve the status quo pursuant to the
22

1 regulations under 42 C.F.R. Part 59 in effect as of the date of this order, until
2 further order of the Court.

3 No bond shall be required pursuant to Federal Rule of Civil
4 Procedure 65(c).

5 It is SO ORDERED.

6 ISSUED this _____ day of _____, 2019.

7

8

THE HONORABLE STANLEY A. BASTIAN

9

Presented by:

10

ROBERT W. FERGUSON
Attorney General

11

12

/s/ Jeffrey T. Sprung
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