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11 IN THE UNITED STATES DISTRICT COURT
 12 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 13

14
 15 **STATE OF CALIFORNIA, by and through**
ATTORNEY GENERAL XAVIER
 16 **BECERRA,**

17 Plaintiff,

18 v.

19 **ALEX AZAR, in his OFFICIAL**
 20 **CAPACITY as SECRETARY of the U.S.**
DEPARTMENT of HEALTH & HUMAN
 21 **SERVICES; U.S. DEPARTMENT of**
HEALTH & HUMAN SERVICES,

22 Defendants.
 23

3:19-cv-01184-EMC

**SUPPLEMENTAL SUBMISSION IN
 SUPPORT OF PLAINTIFF’S MOTION
 FOR PRELIMINARY INJUNCTION**

Administrative Procedure Act Case

Date: April 18, 2019
 Time: 12:30 p.m.
 Dept: Courtroom 5, 17th Floor
 Judge: The Honorable Edward M.
 Chen
 Trial Date: Not set
 Action Filed: March 4, 2019

1 Plaintiff State of California files this supplemental submission in response to the Court’s
 2 April 15, 2019 Order, identifying portions of the available administrative record that will inform
 3 the court on the waiver issue. The majority of these documents are already filed as exhibits to the
 4 Declaration of Anna Rich in support of Plaintiffs’ Motion for Preliminary Injunction (“Rich
 5 Decl.”).¹

6 As a matter of law, an agency has an “obligation to examine its own authority and not to
 7 promulgate implementing regulations in a way that exceeds its scope.” *Sierra Club v. Pruitt*, 293
 8 F. Supp. 3d 1050, 1061 (N.D. Cal. 2018). *See* Cal. Reply Br. at 6, Essential Access, Marshall
 9 Reply Br. at 4. Notwithstanding, here, Defendants had actual notice that the ACA, and specific
 10 requirements embodied in Section 1554, pose significant limitations on HHS’s scope of authority.
 11 *See Nat’l Parks & Conservation Ass’n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir.
 12 2010); Cal. Reply Br. at 5. In addition to the many comments detailed below that address these
 13 issues, Plaintiffs also raised that the Final Rule thwarted the ACA’s goal of integrating healthcare
 14 availability in a meeting with the Office of Management and Budget days before the Final Rule
 15 was published. *See* Declaration of Melanie Fontes Rainer in support of Plaintiffs’ Supplemental
 16 Submission, ¶¶ 2-3.² Thus, the ACA, and all of Section 1554’s restrictions were raised during
 17 rulemaking, including the following comments submitted in response to the proposed rule.

18 I. COMMENTS DISCUSSING THE ACA

19 1. “The passage of the *Patient Protection and Affordable Care Act* (ACA) has been
 20 instrumental in covering a wide-range of preventive services, ensuring that individuals have
 21 access to life-saving screenings and treatment and that women have access to effective and
 22

23 _____
 24 ¹ The Rich Declaration is also attached as Exhibit A to the Declaration of Michelle Ybarra filed in
 support of Plaintiffs Essential Health Access, Inc.’s and Melissa Marshall, M.D.’s Supplemental
 Submission.

25 ² To the extent Defendants contend that Plaintiffs were required to submit comments specifically
 26 mentioning a conflict with Section 1554, Defendants’ abbreviated 30-day comment period did not
 27 give Plaintiffs sufficient time to raise every existing legal challenge, thereby creating “exceptional
 28 circumstances” that warrant Defendants’ waiver argument here. *See Universal Health Services, Inc. v. Thompson*,
 363 F. 3d 1013, 1021 (9th Cir. 2004); Cal. Reply Br. at 6.

1 affordable FDA-approved contraceptive methods.” Rich Decl., Ex. J, American College of Nurse-
2 Midwives at 3.³

3 2. “The proposed definition of what would be considered a ‘medically approved’
4 family planning method under the Title X is not scientific and medically accurate information and
5 if adopted *would effectively limit access and coverage of reproductive health choices expanded*
6 *upon in the ACA* to the detriment of the women and families who rely on the Title X program for
7 these essential health services.” Rich Decl., Ex. J, American College of Nurse-Midwives letter at
8 3.

9 3. “The Affordable Care Act requires that all non-grandfathered health plans cover
10 an HHS-designated list of women’s preventive services, which includes contraceptive services.”
11 Rich Decl. Ex. N, American Academy of Pediatrics and the Society for Adolescent Health and
12 Medicine letter at 10.

13 4. “This proposed change is not only contrary to the Affordable Care Act (ACA), but
14 also is contrary to the intent or capacity of the Title X program.” Rich Suppl. Decl. Ex. B, Black
15 Women’s Health Imperative letter at 4.

16 **II. COMMENTS DISCUSSING UNREASONABLE BARRIERS TO THE**
17 **ABILITY OF INDIVIDUAL TO OBTAIN APPROPRIATE MEDICAL CARE**
18 **(§1554(1))**

19 5. “In effect, the proposed rule could prevent up to 1.6 million women who obtain
20 contraceptive care from Title X-funded Planned Parenthood sites each year from seeing their
21 trusted provider, and in many cases, the only source of care they receive.”⁴ Rich Decl. Ex. C,
22 Center for Reproductive Rights letter at 5-6.

23 6. “The Proposed Rule seeks to *create barriers to access to women’s healthcare,*
24 *including abortion.*” “These *government-imposed barriers* to the physician-patient relationship
25 interfere with the provision of medical care and will impede public health.” Rich Decl. Ex. H,
26 Multistate AG letter at 4, 6.

27 _____
28 ³ Except where otherwise noted, all emphases are added.

⁴ Except where otherwise noted, all emphases are added.

1 7. The proposed rule, “*would create barriers to access* for an even larger number of
2 women nationwide. Access to family planning counseling and a full array of medically accurate
3 sexual and reproductive health services is vital for women’s health and well-being, especially
4 women who wish to avoid or post-pone pregnancy.” Rich Decl., Ex. J, American College of
5 Nurse-Midwives letter at 3.

6 8. The proposed rules, “appear intended to allow Title X projects to deny patients
7 access to the full complement of effective contraceptive methods.” Rich Decl., Ex. K, American
8 Public Health Association letter at 6.

9 9. “On top of implicating these aspects of quality and care coordination, the Proposed
10 Rule would harm patients seeking abortions *by introducing extraordinary difficulties into the*
11 *already arduous process* of obtaining one.” Rich Decl., Ex. M, Planned Parenthood Federation of
12 America letter at 20. *See also id.* at 82 (similar comment).

13 10. “If implemented, the Proposed Rule would *limit access to vital preventive services*
14 for the more than four million patients seeking care annually at a Title X project, including many
15 adolescents and young adults, increasing rates of unplanned pregnancy and other adverse sexual
16 and reproductive health outcomes, undermining public health and turning back the clock on
17 women’s health.” Rich Decl. Ex. N, American Academy of Pediatrics and the Society for
18 Adolescent Health and Medicine letter at 3.

19 11. *See also*, Rich Decl. Ex. D at 2-3; Ex. G at 8; Ex. I at 4; Ex. K at 4-5; Ex. P at 4-5;
20 Ex. Q at 2.

21 **III. COMMENTS DISCUSSING IMPEDIMENTS TO TIMELY ACCESS TO**
22 **HEALTH CARE SERVICES (§1554(2))**

23 12. “*As pregnancy progresses, abortion care becomes more expensive and more*
24 *difficult to obtain. Seemingly minor delays may push a patient into a later stage of pregnancy,*
25 *where fewer providers may be available and procedures may be more complex. The proposed*
26 *rule would result in medically unnecessary and inappropriate delays in care, which are never in*
27 *the best interest of the patient.*” Rich Decl. Ex. C (CRR letter) at 12-13.
28

1 13. “*[R]eproductive health-focused providers are often able to offer more*
2 *comprehensive and more timely family planning services to their patients.* Compared with
3 primary care-focused sites, those focused on reproductive health are more likely to offer the full
4 range of reversible contraceptive methods; to offer same-day insertion of IUDs and implants; to
5 offer supplies of oral contraceptives onsite; to use protocols that help patients start their
6 contraceptive method quickly; and to offer advance provision of emergency contraceptive pills
7 for a client to keep at home.” Rich Decl. Ex. E (Guttmacher letter) at 13-14.

8 14. The gag rule “would prevent Title X providers from sharing complete and accurate
9 medical information necessary *to ensure that their patients are able to make fully informed*
10 *medical decisions and obtain timely care.*” Rich Decl. Ex. G (ACOG letter) at 4, 6.

11 15. “The proposed rule’s drastic changes to pregnancy counseling by Title X providers
12 . . . attempt to enlist clinicians in *deceiving and delaying patients who seek information about or*
13 *access to abortion provider. . .*” Rich Decl., Ex. L National Family Planning & Reproductive
14 Health Association (NFPRHA) at 5.

15 16. “*Forced to delay or forgo basic preventive services* as a result [of Title X
16 providers exiting the program due to the proposed rule], many patients that previously were able
17 to access Title X-funded care from Planned Parenthood or other reproductive health-focused
18 providers would experience adverse health consequences, including unintended pregnancies,
19 undetected STDs, and other poor health outcomes.” Rich Decl., Ex. M, Planned Parenthood
20 Federation of America letter at 33.

21 17. “*This proposed gag on providers will prevent patients from accessing health care*
22 *in a timely manner,* and in turn, lead to negative health outcomes and increased costs associated
23 with delays in care.” Rich Decl. Ex. O, Northeast Valley Health Corporation letter at 2.

24 18. “If all qualified family planning providers that also provide abortion services were
25 to be eliminated from the Title X family planning program in California, 19 California counties
26 would be left without a Title X-funded health center. Many local health systems will have
27 difficulty absorbing the additional patients, *leaving gaps in timely access to care for low-income*
28 *patients across California.*” Rich Decl. Ex. O, Northeast Valley Health Corporation letter at 4.

1 19. See also, Rich Decl. Ex. B at 4-5; Ex. D at 3; Ex. E at 8, 13-14; Ex. H at 8; Ex. I at
2 3.

3 **IV. COMMENTS DISCUSSING INTERFERENCE WITH COMMUNICATIONS**
4 **REGARDING A FULL RANGE OF TREATMENT OPTIONS BETWEEN THE**
5 **PATIENT AND THE PROVIDER (§1554(3))**

6 20. “The NPRM would ban Title X providers from giving women full information
7 about their health care options.” Rich Decl. Ex. B, California Medical Association letter at 2.

8 21. “Even where providers would like to provide the prevailing standard of care, the
9 rule would *prohibit them from providing comprehensive options and referral information,*
10 resulting in additional costs because of service delays and, for some women, unavailability of
11 needed care.” Rich Decl. Ex. C, Center for Reproductive Rights letter at 37-38.

12 22. “The proposed rule *limits how Title X providers can discuss and/or counsel on the*
13 *full-range of sexual and reproductive health care options* with their patients by eliminating the
14 nondirective options for counseling pregnant women that exist under current federal regulation.”
15 Rich Decl., Ex. J, American College of Nurse-Midwives letter at 2.

16 23. “In a meta-analysis of studies examining care management plans, the authors
17 conclude that ‘patient health outcomes can be improved with good physician-patient
18 communication,’ which includes the need for patients to feel ‘that they are active participants in
19 care and that their problem has been discussed fully.’ *Suppressing a provider’s discussion with a*
20 *patient about where and how to access abortion, as per the Department’s proposal, interferes*
21 *with such ‘full discussion.’”* Rich Decl., Ex. M, Planned Parenthood Federation of America letter
22 at 82.

23 24. See also, Rich Decl. Ex. E at 10, 17; Ex. G at 3; Ex. I at 5; Ex. K at 2; Ex. L at 8;
24 Ex. M at 25; Ex. O at 2; Ex. P at 3.

25 **V. COMMENTS RESTRICTING THE ABILITY OF PROVIDERS TO PROVIDE**
26 **FULL DISCLOSURE OF ALL RELEVANT INFORMATION TO PATIENTS**
27 **MAKING HEALTH CARE DECISIONS (§1554(4))**

28 25. “The [gag rule] policy also undermines the right to information by censoring
health care providers from informing patients of all their options related to abortion.” Rich Decl.
Ex. C, Center for Reproductive Rights letter at 41.

1 26. “The Proposed Rule requires physicians to disregard their Code of Medical Ethics
2 and to *tailor their speech to not provide full and accurate healthcare information.*” Rich Decl.
3 Ex. H, Multistate AG letter at 6.

4 27. The proposed rule, “*would restrict midwives who practice at Title X facilities from*
5 *commenting, sharing or passing along critical and medically accurate counseling and*
6 *information to their patients.*” Rich Decl., Ex. J, American College of Nurse-Midwives at 1. “The
7 Proposed Rule directly conflicts with the recommendations of major medical professional
8 associations, including the American College of Obstetricians and Gynecologists and the
9 American College of Physicians, which assert that *patients should receive complete and accurate*
10 *information to inform their health care decisions.*” Rich Decl., Ex. M, Planned Parenthood
11 Federation of America letter at 11.

12 28. *See also*, Rich Decl. Ex. D at 5; Ex. E at 6; Ex. G at 3; Ex. H at 13; Ex. H at 5; Ex.
13 I at 2; Ex. K at 2; Ex. L at 9; Ex. M at 14, 16; Ex. N. at 4; Ex. O at 2; Ex. Q at 1.

14 **VI. COMMENTS DISCUSSING VIOLATION OF THE PRINCIPLES OF**
15 **INFORMED CONSENT AND THE ETHICAL STANDARDS OF HEALTH**
16 **CARE PROFESSIONALS (§1554(5))**

17 29. “*These proposed changes to the [referral] regulations would force Title X providers*
18 *to violate their ethical obligations to their patients.* Providers must provide patients with
19 complete, accurate, and unbiased information about their health care options so that they can
20 make voluntary decisions about their care.” Rich Decl. Ex. B, California Medical Association
21 letter at 4.

22 30. Required parental-involvement “*is not only contrary to medical ethics, but it also*
23 *undermines the relationship between the minor and the health care professional and is likely to*
24 *deter some minors from returning for critical health care services, including family planning and*
25 *testing and treatment for sexually transmitted infections.*” Rich Decl. Ex. C, Center for
26 Reproductive Rights letter at 19.

27 31. “[T]he rule’s proposed ban on abortion referral and its chilling effect (or possibly
28 an effective ban) on abortion counseling are *repudiations of ethical and professional standards*

1 *around informed consent* and have the potential to harm patients and undermine the patient-
2 provider relationship.” Rich Decl. Ex. E, Guttmacher letter at 12, 7.

3 32. “The proposed rule requires Title X clinicians to force unwanted information on
4 and to breach the confidentiality of *patients in violation of longstanding Title X law and medical*
5 *ethics.*” Rich Decl., Ex. L, National Family Planning & Reproductive Health Association letter at
6 9.

7 33. “However, when taking a health history, careful clinicians sometimes learn of
8 circumstances (short of abuse) in a minor’s family that make it not “practicable,” or unrealistic or
9 even harmful, to encourage the minor to involve their parents or guardian. In these situations,
10 they should not be required to take “specific actions” to encourage the minor to do so (and then
11 document those specific actions) as the Proposed Rule requires. *Doing so is not only contrary to*
12 *medical ethics*, but it also undermines the relationship between the minor and the health care
13 professional and is likely to drive some minors away from returning for critical health care
14 services, including contraception and testing and treatment for sexually transmitted infections.”
15 Rich Decl. Ex. N, American Academy of Pediatrics and the Society for Adolescent Health and
16 Medicine letter at 6.

17 34. *See also*, Rich Decl. Ex. D at 4; Ex. G at 1, 14; Ex. H at 10; Ex. I at 1; Ex. J at 2;
18 Ex. K at 5; Ex. L at 4, 5, 8, 9, 21; Ex. M at 10; Ex. O at 1, 2; Ex. Q at 1.

19 **VII. COMMENTS DISCUSSING LIMITATION OF THE AVAILABILITY OF**
20 **HEALTH CARE TREATMENT FOR THE FULL DURATION OF A**
21 **PATIENT'S MEDICAL NEEDS (§1554(6))**

22 35. “*Limiting support for comprehensive reproductive health services takes us back to*
23 *failed policies that harm women’s health.* The gag rule has been associated with an increase in
24 abortions, an increase in maternal deaths and encouraging unsafe abortions.” Rich Decl., Ex. K,
25 American Public Health Association letter at 3.

26 36. “[The] Proposed Rule necessarily reaches activities beyond Title X by limiting the
27 post-conception options medical professionals may provide.” Rich Decl., Ex. M, Planned
28 Parenthood Federation of America letter at 19.

37. *See also*, Rich Decl. Ex. K at 4; Ex. L at 2; Ex. M at 15-16, 18 25, 78-79.

1 **VIII. COMMENTS ADDRESSING THE ACA IN OTHER RULEMAKING**

2 38. Defendants have also acknowledged awareness of Section 1554 of the ACA in
3 separate rule-making and litigation. *See*, Fed. Reg. 57536, 57552 (Nov. 15, 2018).

4 39. Plaintiff Essential Access Health has also raised Section 1554 in previous
5 comments to HHS rulemaking. *See* Supp. Rich Decl. **Exhibit A**.

6 Dated: April 17, 2019

Respectfully Submitted,

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