

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MAINE**

THE FAMILY PLANNING ASSOCIATION OF )  
 MAINE D/B/A MAINE FAMILY PLANNING, )  
 on behalf of itself, its staff, and its patients, *et al.*; )  
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 Plaintiffs, )  
 )  
 v. )  
 )  
 UNITED STATES DEPARTMENT OF )  
 HEALTH AND HUMAN SERVICES, *et al.*; )  
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 Defendants. )  
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Case No. 1:19-cv-00100-LEW

**STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS’  
MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS’  
MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

Pursuant to Local Rule 56(b), Plaintiffs submit the following statement of material facts as to which there is no genuine dispute in support of their Motion for Summary Judgment and Opposition to Defendants’ Motion. Plaintiffs also respond to Defendants’ Statement of Undisputed Material Facts.

**I. Maine Family Planning**

1. Plaintiff Maine Family Planning (“MFP”) was founded in 1971 for the express purpose of competing for, receiving, distributing, and managing the Title X grant for the state of Maine.<sup>1</sup>

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<sup>1</sup> Ex. 1, Declaration of George Hill (“Hill Decl.”) ¶ 5.

2. From 1972 until August 19, 2019, MFP was the sole federal Title X grant recipient in Maine.<sup>2</sup>

3. MFP provides family planning services to approximately 24,000 Mainers annually through a 50-site network headquartered in Augusta and spanning 15 counties, including 18 clinics that it directly controls and operates and 32 sites (often referred to as “subrecipients”) to which it provides funding for family planning.<sup>3</sup>

4. MFP’s network includes: eighteen directly operated sites (located in Augusta, Bangor, Belfast, Calais, Damariscotta, Dexter, Ellsworth, Farmington, Fort Kent, Houlton, Lewiston, Machias, Norway, Presque Isle, Rockland, Rumford, Skowhegan and Waterville); four sites managed by Planned Parenthood of Northern New England (“PPNNE”) (in Portland, Sanford, Topsham, and Biddeford); four federally qualified health centers (“FQHCs”) with 20 clinic sites in total (six of which are located in Portland, and the others are in Bangor, Belgrade, Bethel, Bingham, Brewer, Lovejoy, Madison, Mt. Abram, Old Town, Rangeley, Sheepscot, Strong, Waterville, and Vinalhaven); and five school-based health centers (three in Portland, and one in Readfield, and one in Calais).<sup>4</sup>

5. Many of MFP’s directly-operated clinics and subrecipient sites are located in regions of the state designated by the U.S. Health Resources and Services Administration of the

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<sup>2</sup> *Id.* ¶¶ 1, 5, 24.

<sup>3</sup> *Id.* ¶¶ 1, 10-11, 14.

<sup>4</sup> *Id.* ¶ 10.

federal government as Medically Underserved Areas.<sup>5</sup> MFP provides services in thirteen counties that are more than 50% rural and eight counties that are more than 80% rural.<sup>6</sup>

6. 80% of MFP's patients have incomes under 250% of the federal poverty line, and 78% qualify for free or reduced fee services.<sup>7</sup> Many of MFP's patients have childcare responsibilities and work in low-wage jobs that do not offer paid time off or sick leave.<sup>8</sup> Many of MFP's patients do not have a primary care provider, and MFP's providers are the only health care professionals those patients see.<sup>9</sup>

7. Through its family planning program, MFP offers annual gynecological exams, counseling, contraception, and cancer and sexually transmitted infection screenings, among other services.<sup>10</sup>

8. To support these family planning services, in FY 2018, MFP received Title X grant funding of \$1,929,655, which constituted 39% of its family planning funding and 27% of its overall budget.<sup>11</sup> MFP was awarded \$1,414,000 on September 1, 2018 for a seven-month grant cycle that ended on March 31, 2019.<sup>12</sup>

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<sup>5</sup> *Id.* ¶ 11. See Maine Center for Disease Control & Prevention, *Rural Health & Primary Care*, <https://www.maine.gov/dhhs/mecdc/public-health-systems/rhpc/hpsa.shtml>.

<sup>6</sup> Hill Decl. ¶ 11.

<sup>7</sup> *Id.* ¶ 14.

<sup>8</sup> Ex. 2, Declaration of Evelyn Kieltyka ("Kieltyka Decl.") ¶ 24.

<sup>9</sup> Ex. 8, Declaration of Julie Jenkins ("Jenkins Decl.") ¶ 15.

<sup>10</sup> *Id.* ¶ 6.

<sup>11</sup> Hill Decl. ¶¶ 15-16.

<sup>12</sup> *Id.* ¶ 16.

9. Since 1997, MFP also has provided first-trimester abortion at its clinic in Augusta using private resources, independent from the Title X program.<sup>13</sup> At the time MFP began providing abortion care, it was not yet directly providing any Title X or other family planning services.<sup>14</sup> Up until that point and for the first 15 years of MFP's existence, its function had been solely as an umbrella agency for Title X funds and its role had included management, training, some research, and conducting advocacy and education.<sup>15</sup>

10. MFP's decision to start providing abortion was in response to a growing dearth of abortion services in New England.<sup>16</sup> MFP elected to fill this gap in necessary healthcare for the people of Maine, working closely with the Maine State Attorney General's Office of Civil Rights to facilitate that effort.<sup>17</sup> To that end, MFP identified and purchased a stand-alone building in Augusta to serve as its headquarters that would include a clinical space fully equipped to offer first trimester abortion care.<sup>18</sup> MFP then began to offer, and continues to offer, abortion services in Augusta one day per week.<sup>19</sup>

11. In 1997, MFP also decided to end its subcontract with the local agency providing family planning services in Augusta, and to hire its family planning staff in order to begin

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<sup>13</sup> *Id.* ¶¶ 7, 8.

<sup>14</sup> *Id.* ¶ 6.

<sup>15</sup> *Id.* ¶¶ 6-7.

<sup>16</sup> *Id.* ¶ 7.

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

directly providing Title X services.<sup>20</sup> MFP decided to provide those family planning services at its new headquarters site, where it was already providing abortion care services.<sup>21</sup> MFP began offering Title X services in its Augusta building in July 1998, a year after its initiation of abortion services.<sup>22</sup>

12. A considerable factor in MFP's decision to co-locate Title X and abortion services was the example being set by larger health care providers throughout the country, many of which were consolidating services in single locations to provide patients streamlined and efficient healthcare.<sup>23</sup> Had MFP not been permitted by the Title X regulations to co-locate its family planning and abortion services, it would not have chosen to consolidate these services into a single physical building.<sup>24</sup>

13. Over the course of the following decade, MFP also took direct control over other family planning clinics. By 2012, MFP directly managed the 18 clinical sites that it continues to directly manage today.<sup>25</sup>

14. MFP now offers abortion at all 18 of its directly-controlled clinics, at which it also separately provides family planning services.<sup>26</sup>

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<sup>20</sup> *Id.* ¶ 8.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*; Ex. 3, Declaration of Martha J. Bailey ("Bailey Decl.") ¶ 50.

<sup>24</sup> Hill Decl. ¶ 8.

<sup>25</sup> *Id.* ¶ 9.

<sup>26</sup> *Id.* ¶ 24, 24, 38.

15. At all times since MFP began providing abortion at its clinics, MFP's abortion care has been funded privately and kept financially separate from its family planning services.<sup>27</sup>

16. Aspiration abortions through 14.0 weeks, as dated from the first day of the patient's last menstrual period ("LMP"), and medication abortions through 11.0 weeks are provided one day a week at MFP's Augusta clinic, a day on which no family planning activities take place.<sup>28</sup>

17. MFP also offers medication abortion through 11.0 weeks at its 17 satellite clinics.<sup>29</sup>

18. In total, MFP provides approximately 500 abortions a year, of which approximately 25% are provided outside of the Augusta clinic.<sup>30</sup> In 2010, 48% of pregnancies in Maine were unintended.<sup>31</sup>

19. Besides MFP, the only other places in Maine where medication and aspiration abortion services are publicly available (i.e., generally open to new patients) are: (1) PPNE in Portland; and (2) the Mabel Wadsworth Center in Bangor.<sup>32</sup> Each of these sites generally provides abortion only one day a week.<sup>33</sup>

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<sup>27</sup> *Id.* ¶¶ 7-8, 24-30.

<sup>28</sup> Kieltyka Decl. ¶ 18; Hill Decl. ¶ 7.

<sup>29</sup> Kieltyka Decl. ¶¶ 16, 19; Hill Decl. ¶ 38.

<sup>30</sup> Kieltyka Decl. ¶ 19; Hill Decl. ¶ 38.

<sup>31</sup> Bailey Decl. ¶ 56.

<sup>32</sup> Kieltyka Decl. ¶ 20.

<sup>33</sup> *Id.*

20. MFP has never been found in violation of any Title X requirements either by government auditors or by its own internal oversight.<sup>34</sup>

21. One study estimated that in 2010, Maine's publicly funded family planning services reduced federal and state government costs by \$33.6 million.<sup>35</sup>

## **II. Plaintiffs' Experts**

22. Dr. Martha J. Bailey is a Professor of Economics at the University of Michigan and member of the executive boards of the American Economics Association and Board of the Society of Labor Economists.<sup>36</sup> Dr. Bailey has conducted extensive research on the historical, economic, and social impact that family planning services have had on American society.<sup>37</sup> Dr. Bailey opines on the effects of "Compliance With Statutory Program Integrity Requirements" ("the Rule")<sup>38</sup> on the Title X program based on her research on the historical, economic, and social impact that family planning services have had on American society.<sup>39</sup>

23. Dr. Mathew Wynia is the Director of the Center for Bioethics and Humanities at the University of Colorado and directed the American Medical Association's Institute for Ethics from 2000 to 2013.<sup>40</sup> He has held many other positions focused on medical ethics, and has

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<sup>34</sup> Hill Decl. ¶¶ 24-30.

<sup>35</sup> Bailey Decl. ¶ 59.

<sup>36</sup> *Id.* ¶¶ 1-3.

<sup>37</sup> *Id.* ¶¶ 6-9.

<sup>38</sup> Compliance with Statutory Program Integrity Requirements [hereinafter "Final Rule"], 84 Fed. Reg. 7,714 (Mar. 4, 2019) (to be codified at 42 C.F.R. pt. 59).

<sup>39</sup> Bailey Decl. ¶ 10.

<sup>40</sup> Ex. 4, Declaration of Matthew Wynia ("Wynia Decl.") ¶¶ 1-10.

published more than 150 peer-reviewed articles on medical ethics.<sup>41</sup> Dr. Wynia opines on the effects of the Rule on the ethical obligations of healthcare providers within the Title X program.<sup>42</sup>

24. Dr. Jason Lindo is a Professor of Economics at Texas A&M University, where he teaches courses on quantitative methods that economists use to evaluate the causal effects of government programs and other interventions.<sup>43</sup> Dr. Lindo has also been employed at the National Bureau of Economic Research since 2011 and has published extensively in the research areas of health economics, public economics, and policy evaluation.<sup>44</sup> Dr. Lindo opines on the empirical effects of the Rule on abortion access in Maine.<sup>45</sup>

### **III. Title X**

25. Congress created Title X in 1970 with the goal of making “comprehensive voluntary family planning services readily available to all,” “enabl[ing] public and nonprofit private entities to plan and develop comprehensive [family planning] programs,” and funding related research and training.<sup>46</sup> Title X is the only federal program specifically dedicated to funding family planning services.<sup>47</sup> Unlike fee-for-service programs like Medicaid, Title X grant money is provided in a lump sum and may be used by the grantee both to cover the costs of

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<sup>41</sup> *Id.*

<sup>42</sup> *Id.* ¶ 11.

<sup>43</sup> Ex. 5, Declaration of Jason Lindo (“Lindo Decl.”) ¶¶ 1-6.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* ¶ 7.

<sup>46</sup> Family Planning Services and Population Research Act, Pub. L. 91-572, 84 Stat. 1504 §2 (1970).

<sup>47</sup> 42 U.S.C. §§ 300 to 300a-6; Bailey Decl. ¶¶ 15-17.

family planning care for the un- or under-insured and to pay for non-service costs like purchasing contraceptives or training staff.<sup>48</sup> Title X funds may not be used to pay for abortion services.<sup>49</sup>

26. The core of Title X's mission is the expansion of access to reproductive health care services to low-income individuals, including communities of color, immigrants, and rural residents who may otherwise lack access to family planning services and related preventive care.<sup>50</sup>

27. Title X is a competitive grant program, meaning that eligible entities must apply to the Office of Population Affairs ("OPA") in the Department of Health and Human Services ("HHS") to be awarded funds.<sup>51</sup> Prior to the implementation of the Rule, there were 3,954 sites across the country serving around four million patients.<sup>52</sup> Site operators included government health departments, hospitals, Planned Parenthood health centers, federally qualified health centers ("FQHCs"), and other private non-profit organizations like MFP.<sup>53</sup> The United States Centers for Disease Control and Prevention ("CDC") has hailed Title X as one of the greatest public health achievements of the 20th Century.<sup>54</sup>

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<sup>48</sup> 42 U.S.C. § 300.

<sup>49</sup> *Id.* § 300a-6.

<sup>50</sup> Family Planning Services and Population Research Act, Pub. L. No. 91-572, 84 Stat. 1504 §2 (1970); 42 U.S.C. §300(a).

<sup>51</sup> 42 C.F.R. §§ 59.3-4.

<sup>52</sup> Bailey Decl. ¶¶ 27-28.

<sup>53</sup> *Id.* ¶¶ 28, 37, 39.

<sup>54</sup> CDC, *Achievements in Public Health, 1990–1999: Family Planning*, 48 MORBIDITY & MORTALITY WKLY. REP. 1073, 1073 (1999).

28. For the past 15 years, roughly two-thirds of Title X patients had incomes at or below the poverty level.<sup>55</sup> And in 2018, 89% of patients qualified for either subsidized or no-charge services.<sup>56</sup>

29. Title X programs are not funded exclusively by Title X; by law, they cannot be.<sup>57</sup> In 2018, Title X funding itself accounted nationwide for 19% of Title X project revenue, with the remainder coming from fees for service and other government grants.<sup>58</sup>

30. Title X grantees are subject to regular and extensive compliance review by HHS.<sup>59</sup> According to OPA, “family planning projects that receive Title X funds are closely monitored to ensure that federal funds are used appropriately and that funds are not used for prohibited activities such as abortion.”<sup>60</sup> As identified by HHS, there are several “safeguards” in place to ensure abortion activities are kept “separate and distinct” from Title X programs, including:

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<sup>55</sup> *Id.* ¶ 31.

<sup>56</sup> *Id.*

<sup>57</sup> 42 C.F.R. §59.7(c).

<sup>58</sup> OFFICE OF POPULATION AFFAIRS, FAMILY PLANNING ANNUAL REPORT: 2018 NATIONAL SUMMARY 53 (Aug. 2019) [hereinafter 2018 FPAR], <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2018-national-summary.pdf>.

<sup>59</sup> Hill Decl. ¶¶ 24-30.

<sup>60</sup> ANGELA NAPILI, CONG. RESEARCH SERV., TITLE X (PUBLIC HEALTH SERVICE ACT) FAMILY PLANNING PROGRAM 22 (Aug. 31, 2017) [hereinafter 2017 CRS REPORT], <https://fas.org/sgp/crs/misc/RL33644.pdf>; ANGELA NAPILI, CONG. RESEARCH SERV., TITLE X (PUBLIC HEALTH SERVICE ACT) FAMILY PLANNING PROGRAM 16 (Oct. 15, 2018) [hereinafter 2018 CRS REPORT], <https://fas.org/sgp/crs/misc/R45181.pdf>.

(1) careful review of grant applications to ensure that the applicant understands the requirements and has the capacity to comply with all requirements; (2) independent financial audits to examine whether there is a system to account for program-funded activities and nonallowable program activities; (3) yearly comprehensive reviews of the grantees' financial status and budget report; and (4) periodic and comprehensive program reviews and site visits by OPA regional offices.<sup>61</sup>

Grantees also are responsible for monitoring their sub-recipients' financial compliance on an ongoing basis and must get pre-approval from OPA for any changes in the scope of their Title X project or new sub-recipient contracting relationships.<sup>62</sup>

31. As of 2016, around 60% of women receiving Title X services reported that a Title X-funded health center was their usual source of medical care.<sup>63</sup>

32. Many patients prefer Title X clinics over other providers of family planning services because they find that Title X-funded sites offer more effective types of contraception and better contraceptive counseling than other health centers or publicly-funded clinics; provide a greater variety of services on site; and have better same-day and walk-in appointment availability.<sup>64</sup>

33. A study estimated that in 2015, Title X funds helped provide sexually transmitted infection ("STI") tests preventing over 50,000 chlamydia infections, nearly 9,000 gonorrhea infections, 1,900 cases of cervical cancer, and 1,660 cases of infertility.<sup>65</sup>

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<sup>61</sup> 2017 CRS REPORT, *supra* note 58, at 22.

<sup>62</sup> 42 C.F.R. pt. 59; Hill Decl. ¶¶ 24-30.

<sup>63</sup> Bailey Decl. ¶ 27 & n.39.

<sup>64</sup> *Id.* ¶¶ 46-50.

<sup>65</sup> *Id.* ¶ 53.

34. One study estimated that in 2015, the contraceptive care delivered by Title X–funded clinics helped avoid 822,300 unintended pregnancies, which would have resulted in 387,000 unplanned births and 278,000 abortions.<sup>66</sup>

35. Because Section 1008 of Title X of the Public Health Services Act provides that “[n]one of the funds appropriated under [Title X] shall be used in programs where abortion is a method of family planning,”<sup>67</sup> in 1971 HHS issued regulations barring Title X grantees from providing “abortions as a method of family planning.”<sup>68</sup> Throughout the 1970s and 80s, HHS took the position that the provision of information about abortion, including referral to abortion providers, was permissible activity for a Title X grantee, while “directive” counseling that encouraged or promoted abortion, as in by providing transportation to the patient, was not.<sup>69</sup>

36. With one exception in the late 1980s, the regulations governing Title X have always allowed Title X projects to share facilities with abortion providers,<sup>70</sup> and have required Title X providers to offer “nondirective” options counseling to pregnant women and referrals for abortion services upon request.<sup>71</sup> These requirements were formalized in 2000.<sup>72</sup>

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<sup>66</sup> *Id.* ¶ 52.

<sup>67</sup> 42 U.S.C. § 300a-6.

<sup>68</sup> Grants for Family Planning Services, 36 Fed. Reg. 18,465, 18,466 (Sept. 15, 1971) (codified at 42 C.F.R. pt. 59 (1972)).

<sup>69</sup> See *Nat’l Family Planning & Reprod. Health Ass’n, Inc., v. Sullivan*, 979 F.2d 227, 229 (D.C. Cir. 1992).

<sup>70</sup> See Standards of Compliance for Abortion-Related Services in Family Planning Services Projects, 65 Fed. Reg. 41,270 [hereinafter “2000 Rule”], 41,272-73, 41,275 (July 3, 2000) (codified at 42 C.F.R. pt. 59).

<sup>71</sup> *Id.* at 41,275.

<sup>72</sup> *Id.* at 41270, 41,272-73, 41,275.

37. “Nondirective counseling” is commonly understood in medicine to mean patient-centered counseling that presents neutral and unbiased information regarding all options relevant to the patient and consistent with the patient’s expressed wishes to hear the information, including in the context of pregnancy, prenatal care, adoption, and/or abortion.<sup>73</sup>

38. In 1988, HHS issued a rule (“the 1988 Rule”) that prohibited Title X recipients who refer for or counsel on abortion care from receiving federal family planning funds, and required physical and financial separation of Title X services from abortion services and ancillary abortion-connected services.<sup>74</sup> The 1988 Rule was initially enjoined, but the United States Supreme Court, in *Rust v. Sullivan*, 500 U.S. 173 (1991), ultimately held that it was facially lawful.<sup>75</sup>

39. In November 1991, in response to ongoing outcry from the medical community, President George H.W. Bush directed HHS to implement the 1988 Rule in a manner that would permit counseling on abortion.<sup>76</sup> Because the guidelines then issued by HHS permitted physicians, but not nurse practitioners, to counsel on abortion services, they were challenged again.<sup>77</sup> Ultimately, in November 1992, the D.C. Circuit upheld an injunction preventing the guidelines from being enforced for failure to follow notice-and-comment requirements.<sup>78</sup>

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<sup>73</sup> Wynia Decl. ¶ 13; *see also* Kieltyka Decl. ¶ 30, 36.

<sup>74</sup> Statutory Prohibition on Use of Appropriated Funds In Programs Where Abortion Is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects, 53 Fed. Reg. 2,922 (Feb. 2, 1988) (codified at 42 C.F.R. pt. 59).

<sup>75</sup> Final Rule, 84 Fed. Reg. at 7,721.

<sup>76</sup> *Nat’l Family Planning and Reprod. Health Assoc., Inc. v. Sullivan*, 979 F.2d at 230.

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

40. In response to the 1988 Rule, in September 1992, Congress passed a bill that explicitly allowed abortion counseling within Title X, the Family Planning Amendments Act of 1992 (“FPAA”).<sup>79</sup> The FPAA would have required counseling and referral on all pregnancy options, including prenatal care and delivery, infant care, foster care, adoption, and pregnancy termination.<sup>80</sup> After then-President Bush vetoed the FPAA,<sup>81</sup> Congress responded by including similar language in its appropriations bill for Title X, requiring that “all pregnancy counseling shall be nondirective” (the Nondirective Counseling Mandate) alongside the statement that “amounts provided to [Title X] projects . . . shall not be expended for abortions.”<sup>82</sup> This language has been included every year since 1996.<sup>83</sup>

41. In passing the FPAA, members of Congress described the 1988 Rule as, *inter alia*, “bad medicine, bad law, and bad precedent” and as “a step toward two-tier health care in America.”<sup>84</sup> Congressman Studds stated:

When we created the title X program 20 years ago, we did not intend to muzzle health care providers. But we didn't say that loudly and clearly enough. But this time, let there be no mistake. Title X providers must be able to inform individuals of all pregnancy management options and we must write this explicitly into law.<sup>85</sup>

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<sup>79</sup> S. 323, 102nd Cong. (1992).

<sup>80</sup> See 138 Cong. Rec. H 9862 (Apr. 30, 1992) (statement of Rep. Lloyd).

<sup>81</sup> S.102-28, 102nd Cong. (1992).

<sup>82</sup> See, e.g., Continuing Appropriations Act, 2019, Pub. L. 115-245, 132 Stat. 2981, 3070-71 (2018).

<sup>83</sup> *Id.*

<sup>84</sup> *Id.* at 9859 (statement of Rep. Waxman); *Id.* at 9860 (statement of Rep. Wyden).

<sup>85</sup> 138 Cong. Rec. at 9872.

42. President George H.W. Bush vetoed the FPAA, and Congress was unable to override the veto.<sup>86</sup>

43. The 1988 Rule never went into full effect before being suspended in 1993.<sup>87</sup> Upon the 1988 Rule's suspension, the previously governing regulations and standards were put back into effect.<sup>88</sup>

44. HHS subsequently issued regulations in 2000 that explained that it was the Department's position that "requiring a referral for prenatal care . . . where the client rejected th[at] option[] would seem coercive and inconsistent with the concerns underlying the 'nondirective' counseling requirement."<sup>89</sup> The regulations issued in 2000 required Title X projects to provide pregnant women with "neutral, factual information and nondirective counseling on each of [her] options, and referral on request, except with respect to any option(s) about which the pregnant woman indicates she does not wish to receive such information and counseling."<sup>90</sup>

45. In 2014, HHS created a set of Quality Family Planning guidelines ("2014 QFP"), which are incorporated into the Title X program; the evidence-based 2014 QFP requires that "[pregnancy] test results should be presented to the client, followed by a discussion of options

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<sup>86</sup> S.102-28, 102nd Cong. (1992).

<sup>87</sup> Standards of Compliance for Abortion-Related Services in Family Planning Service Projects, 58 Fed. Reg. 7462, 7462 (Feb. 5, 1993) (codified at 42 C.F.R. pt. 59).

<sup>88</sup> *Id.*

<sup>89</sup> 2000 Rule, 65 Fed. Reg. at 41,275.

<sup>90</sup> 42 C.F.R. § 59.5(a)(5)(ii) (2000); *see* 2000 Rule, 65 Fed. Reg. at 41,279.

and appropriate referrals” consistent with the recommendations of professional medical organizations.<sup>91</sup>

46. Additionally, in 2010, Congress passed Section 1554 of the Patient Protection and Affordable Care Act (“ACA”), which reads:

Notwithstanding any other provision of this Act, the Secretary of Health and Human Services shall not promulgate any regulation that— (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; (3) interferes with communications regarding a full range of treatment options between the patient and the provider; (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions; (5) violates the principles of informed consent and the ethical standards of health care professionals; or (6) limits the availability of health care treatment for the full duration of a patient’s medical needs.<sup>92</sup>

#### **IV. HHS’s New Separation and Gag Rule**

##### **A. Proposal and Review of New Rule**

47. On May 22, 2018, HHS released a notice of proposed rulemaking (“Proposed Rule”), reversing its longstanding policy and largely reinstating the 1988 Rule, including provisions that limit, and in many circumstances ban, Title X recipients from providing their patients with referral and counseling for abortion services, and provisions that require strict physical separation between abortion services and Title X services.<sup>93</sup>

48. HHS received over 500,000 comments in response to the Proposed Rule.<sup>94</sup>

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<sup>91</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVS., PROVIDING QUALITY FAMILY PLANNING SERVICES 14 (Apr. 25, 2014), <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf>.

<sup>92</sup> 42 U.S.C. § 18114 (2012).

<sup>93</sup> Compliance with Statutory Program Integrity Requirements, 83 Fed. Reg. 25,502 [hereinafter “Proposed Rule”] (proposed June 1, 2018) (to be codified at 42 C.R.F. pt. 59).

<sup>94</sup> Final Rule, 84 Fed. Reg. at 7,722.

49. Among many other organizations opposing the Rule, most major medical associations—including the American Medical Association (“AMA”), the American College of Obstetricians and Gynecologists (“ACOG”), the American College of Physicians, the American Academy of Family Physicians (“AAFP”), the American Academy of Nursing (“AAN”), and the American Academy of Pediatrics (“AAP”)—submitted comments in opposition.<sup>95</sup>

50. These professional organizations opposed the Proposed Rule for numerous reasons, including because it would interfere with the relationship between patients and their health care providers, threaten patient confidentiality, undermine patients’ access to evidence-based family planning methods, exclude providers that separately offer abortion services from receiving Title X funds, and restrict patients’ access to care.<sup>96</sup>

51. By contrast, as Defendants have conceded, no professional organization has taken the position that the Proposed Rule and ultimately the Final Rule are consistent with medical ethics.<sup>97</sup>

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<sup>95</sup> Am. Med. Ass’n Letter [hereinafter “AMA Letter”], AR 269330; Am. Coll. of Obstetricians & Gynecologists Letter [hereinafter “ACOG Letter”], AR 268836; Am. Coll. of Physicians Letter [hereinafter “ACP Letter”], AR 281203; Am. Acad. of Family Physicians Letter [hereinafter “AAFP Letter”], AR 104075; Am. Acad. of Nursing Letter [hereinafter “AAN Letter”], AR 107970; Am. Acad. of Pediatrics & Soc’y for Adol. Health & Med. Letter [hereinafter “AAP Letter”], AR 277786.

<sup>96</sup> See *supra* note 95.

<sup>97</sup> Ex. 6, Transcript of January 27, 2020 Hearing on Cross Motions for Summary Judgment, *Mayor and City Council of Baltimore v. Azar, et al.*, No. RDB-19-cv-1103, at M25-26, attached as Exhibit to the Declaration of Emily Nestler.

52. Numerous members of the U.S. Senate<sup>98</sup> and House of Representatives,<sup>99</sup> as well as several states,<sup>100</sup> spoke out against the Proposed Rule, citing detrimental effects the proposed changes would have on the Title X program.<sup>101</sup> In total, nearly 200 legislators submitted comments opposing the Proposed Rule.<sup>102</sup>

53. Major Title X providers, including Planned Parenthood,<sup>103</sup> and policy and research organizations such as the Guttmacher Institute,<sup>104</sup> the American Civil Liberties Union,<sup>105</sup> and the National Family Planning & Reproductive Health Association,<sup>106</sup> described significant negative impacts the Proposed Rule would likely have on patients, particularly members of vulnerable populations, including women of color, LGBTQ+ patients, and victims of intimate partner violence.<sup>107</sup> These comments and others cited to empirical studies, case studies, and other research indicating that dramatically unfavorable outcomes were likely to result from the Proposed Rule.<sup>108</sup> In addition, a number of organizations representing public health

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<sup>98</sup> 25 U.S. Senators Letter, AR 108713.

<sup>99</sup> 173 Members of the House of Representatives Letter [hereinafter “Members of the House Letter”], AR 281722.

<sup>100</sup> *See, e.g.*, 14 Democratic Governors Letter, AR 388077; Letter from Andrew M. Cuomo, Governor, State of New York [hereinafter “N.Y. Letter”], AR 239318; Letter from Jay Inslee, Governor, State of Washington, AR 306310; Letter from Bruce S. Anderson, Director of Health, State of Hawaii Department of Health, AR 306310.

<sup>101</sup> *See supra* notes 98-100.

<sup>102</sup> *See supra* notes 98-100.

<sup>103</sup> *See, e.g.*, Planned Parenthood Action Fund Letter [hereinafter “PPAF Letter”], AR 316400.

<sup>104</sup> Guttmacher Institute Letter [hereinafter “Guttmacher Letter”], AR 264415.

<sup>105</sup> American Civil Liberties Union Letter [hereinafter “ACLU Letter”], AR 305722.

<sup>106</sup> National Family Planning & Reproductive Health Ass’n Letter, AR 308011.

<sup>107</sup> *See supra* notes 103-106.

<sup>108</sup> *See supra* notes 103-106.

professionals<sup>109</sup> and community health centers,<sup>110</sup> along with thousands of individual Americans from across the country submitted comments expressing grave concerns about the Proposed Rule as drafted.<sup>111</sup> Some commenters organized their submissions through organizations such as CREDO Action.<sup>112</sup> Many others submitted comments directly, taking the opportunity to express the impact of Title X services on their lives and the harm the Proposed Rule would cause.<sup>113</sup> To provide just one of many examples, one woman described her reliance on MFP's confidential Title X services as a teenager and visiting with her daughters for a contraceptive visit.<sup>114</sup>

54. Many commenters provided evidence that speaks to harms prohibited by Section 1554: they described unreasonable barriers to care,<sup>115</sup> impediments to timely care access,<sup>116</sup> interference with communications regarding treatment options,<sup>117</sup> restriction on full disclosure of all relevant information to patients,<sup>118</sup> and violations of ethical standards of healthcare professionals.<sup>119</sup>

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<sup>109</sup> *E.g.*, American Public Health Ass'n Letter, AR 239893.

<sup>110</sup> *E.g.*, National Ass'n of Community Health Centers, AR 263270.

<sup>111</sup> *See infra* notes 112-113.

<sup>112</sup> *E.g.*, CREDO Action Letter, AR 331620 (attaching 51,018 comments from individuals opposing the Proposed Rule).

<sup>113</sup> *See, e.g.*, Letter from Jodi Bolduc, AR 90682.

<sup>114</sup> *Id.*

<sup>115</sup> *See, e.g.*, N.Y. Letter, *supra* note 100, at AR 239322.

<sup>116</sup> *See, e.g.*, PPAF Letter, *supra* note 103, at AR 316430-316431.

<sup>117</sup> *See, e.g.*, AMA Letter, *supra* note 95, at AR 269332.

<sup>118</sup> *See, e.g.*, N.Y. Letter, *supra* note 100, at AR 239324.

<sup>119</sup> *See, e.g.*, AMA Letter, *supra* note 95, at AR 269332; ACOG Letter, *supra* note 95, at 268840; AAFP Letter, *supra* note 95, AR 104075; AAN Letter, *supra* note 95, at AR 107973.

55. The Proposed Rule received negative responses from Maine-based organizations that submitted comments, such as MFP,<sup>120</sup> the American Civil Liberties Union of Maine,<sup>121</sup> and the Maine Section of ACOG.<sup>122</sup> These organizations submitted comments describing the disproportionate impact the Proposed Rule would have on residents of Maine, which the U.S. Census Bureau has deemed the nation's most rural state.<sup>123</sup> Organizations local to the state, including Maine Equal Justice Partners,<sup>124</sup> Grandmothers for Reproductive Rights,<sup>125</sup> and the Maine Coalition Against Sexual Assault<sup>126</sup> also articulated their opposition to the Proposed Rule.<sup>127</sup>

56. On March 4, 2019, HHS published final regulations that are largely identical to the Proposed Rule, Compliance With Statutory Program Integrity Requirements (the "Rule").<sup>128</sup>

57. Compliance with the Rule's physical separation requirements will be required within one year of publication of the final Rule, on March 4, 2020.<sup>129</sup> The other portions of the

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<sup>120</sup> Family Planning Ass'n of Maine Letter, AR 239553.

<sup>121</sup> American Civil Liberties Union of Maine Letter, AR 270274.

<sup>122</sup> Maine Section of the American College of Obstetricians & Gynecologists Letter, AR 279990.

<sup>123</sup> U.S. CENSUS BUREAU, MAINE: 2010 POPULATION AND HOUSING UNIT COUNTS 2 (2010); Press Release, U.S. Census Bureau, Growth in Urban Population Outpaces Rest of Nation (Mar. 26, 2012).

<sup>124</sup> Maine Equal Justice Partners Letter, AR 331492.

<sup>125</sup> Grandmothers for Reproductive Rights Letter, AR 244973.

<sup>126</sup> Maine Coalition Against Sexual Assault Letter, AR 278775.

<sup>127</sup> *See supra* notes 124-126.

<sup>128</sup> Final Rule, 84 Fed. Reg. at 7,714.

<sup>129</sup> *Id.*

Rule had earlier requirements for compliance, and each of those other portions is now in effect.<sup>130</sup>

**B. Referral Prohibition and Counseling Restrictions (the “Gag Rule”)**

58. In a section of the Rule captioned “Prohibition on referral for abortion,” the Rule states that “[a] Title X project may not perform, promote, refer for, or support abortion as a method of family planning, nor take any other affirmative action to assist a patient to secure such an abortion.”<sup>131</sup> Under this provision, no information about abortion providers, identified as such, may be provided to a patient.<sup>132</sup> This bar on providing information about abortion providers includes both written information, such as a list of available abortion providers, and oral information or counseling about which abortion provider could meet a patient’s particular needs and why.<sup>133</sup> Under the provision, even when a pregnant patient explicitly requests a referral for abortion, a health care provider is prohibited from speaking to their patient about their referral options.<sup>134</sup>

59. The Rule allows the medical professional to provide the patient with “a list” of “licensed, qualified, comprehensive primary health care providers (including providers of prenatal care), some, but not the majority, of which also provide abortion as part of their comprehensive health care services.”<sup>135</sup> The list thus may include abortion providers, but only if

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<sup>130</sup> *Id.* at 7,714, 7,763, 7,775.

<sup>131</sup> *Id.* at 7,788-89.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 7,789.

<sup>134</sup> *Id.*

<sup>135</sup> *Id.*

those abortion providers also offer comprehensive primary health care services.<sup>136</sup> Health professionals are prohibited from including on the list any providers who only offer abortion services, even if those are the only abortion providers in the region.<sup>137</sup> Further, while the list “may” include abortion providers, it does not need to include any, even if a patient explicitly asks for a referral to an abortion provider.<sup>138</sup>

60. By these terms, the Rule requires Title X providers to withhold the identities of most abortion providers, since most abortion providers do not also offer the full spectrum of primary care.<sup>139</sup> In sum, when a patient seeks an abortion referral, the most information she may receive in response to that request is a list of providers that must: (1) include a majority of health care providers who will not offer the patient the care she seeks; and (2) exclude providers who can offer abortion care because they do not also offer other services that are unnecessary for the patient.<sup>140</sup>

61. Even when an abortion provider is included on the allowable “list,” the list “cannot be used to indirectly refer for abortion or to identify abortion providers to a client,”<sup>141</sup> and the Rule makes explicit that “[n]either the list nor project staff may identify which providers on the list perform abortion.”<sup>142</sup> Medical professionals may not tell their patients that the list is

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<sup>136</sup> *Id.*

<sup>137</sup> *Id.*

<sup>138</sup> *Id.*

<sup>139</sup> Kieltyka Decl. ¶¶ 32-35; Bailey Decl. ¶ 123; Wynia Decl. ¶¶ 23-27.

<sup>140</sup> Final Rule, 84 Fed. Reg. 7,789; Kieltyka Decl. ¶¶ 32-35; Wynia Decl. ¶¶ 23-29.

<sup>141</sup> Final Rule, 84 Fed. Reg. 7,761.

<sup>142</sup> *Id.* at 7,789; Kieltyka Decl. ¶¶ 33-34.

responsive to their request for a referral to an abortion provider at all, much less which provider on the “list” performs abortions or that there are other, more appropriate abortion care options available, even if the patient specifically asks for this information.<sup>143</sup>

62. The Rule requires providers to withhold medical advice about which abortion providers are most appropriate for their patients’ needs and medical circumstances.<sup>144</sup> Whether a given abortion provider is suitable for a particular patient requires assessment of the patient’s medical condition, location, preferences, and other needs, an assessment that is best made with assistance from an informed health care professional rather than by a patient alone.<sup>145</sup>

63. By prohibiting abortion referrals in this manner, the Rule expressly requires Title X providers to withhold medically-relevant information, known to the provider, that a reasonable patient with an unwanted pregnancy would want or need.<sup>146</sup>

64. In Maine, if a family planning patient in Augusta sought an abortion referral, the referral ban would limit the provider to giving the patient a list of primary care providers, only one of which—located 80 miles away in Bangor—provides the requested service—although MFP’s nearby facility could meet the patient’s needs.<sup>147</sup>

65. At the same time the Rule prohibits abortion referrals, the Rule also mandates that the staff of Title X providers must provide all pregnant patients with a referral to prenatal services, regardless of whether the patient has requested such a referral, and even if it is against

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<sup>143</sup> Kieltyka Decl. ¶¶ 33-34; Wynia Decl. ¶¶ 25-27.

<sup>144</sup> Ex. 7, Declaration of MFP Nurse Practitioner (“NP Decl.”) ¶ 18; Jenkins Decl. ¶¶ 13-15; Wynia Decl. ¶¶ 26-29.

<sup>145</sup> Wynia Decl. ¶ 17, 23-29; Kieltyka Decl. ¶¶ 30-32; Jenkins Decl. ¶ 14.

<sup>146</sup> Wynia Decl. ¶¶ 23-27; Jenkins Decl. ¶¶ 13-15.

<sup>147</sup> Kieltyka Decl. ¶¶ 34.

the medical judgment of the health professional to provide that prenatal referral to that particular patient absent any such request.<sup>148</sup> The preamble to the Rule states that the reason for this requirement is Defendants' conclusion that prenatal referrals are "medically necessary for the health of the pregnant mother, as well as the unborn baby."<sup>149</sup> The Rule does not explain why or how prenatal care is "medically necessary" for a woman seeking an abortion.<sup>150</sup>

66. The Rule states that a Title X provider "may also choose to provide" what it terms "nondirective pregnancy counseling."<sup>151</sup> The Rule defines "nondirective pregnancy counseling" as giving a Title X provider the option to inform pregnant patients only about prenatal care and adoption, without providing any information about abortion, including, but not limited to, the availability of abortion and whether abortion is an option for that patient.<sup>152</sup>

67. Under the Rule's definition of "nondirective counseling," if a Title X provider does provide any information about abortion, such counseling may only be provided by physicians or advanced practice providers ("APPs"),<sup>153</sup> and then only if he or she also provides information about at least one other option (prenatal care or adoption) in conjunction with any counseling about abortion.<sup>154</sup> Under those circumstances, the doctor or APP is required to provide information about prenatal care or adoption, regardless of whether the patient wants or

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<sup>148</sup> Final Rule, 84 Fed. Reg. 7,789; Wynia Decl. ¶¶ 25-29; Jenkins Decl. ¶¶ 19-21; Kieltyka Decl. ¶ 32.

<sup>149</sup> Final Rule, 84 Fed. Reg. 7,728, 7,789.

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.* at 7,747.

needs that additional information, and even if the patient explicitly asks that it not be provided.<sup>155</sup>  
The provider must also include a prenatal referral.<sup>156</sup>

68. The Rule defines APP to mean “a medical professional who receives at least a graduate level degree in the relevant medical field and maintains a license to diagnose, treat, and counsel patients. The term [APP] includes physician assistants and advanced practice registered nurses.”<sup>157</sup> Under the Rule, no medical professionals who fall outside this definition, other than physicians, may provide information to patients about abortion, even if it is in the form of “nondirective counseling” as defined by the Rule.<sup>158</sup>

69. As a result of the Rule’s definition of APP and its associated restrictions on abortion counseling by other medical professionals, other midlevel health care professionals may not provide any counseling that discusses abortion, regardless of whether they are qualified and trained to do so.<sup>159</sup>

70. The Rule does not address the fact that qualified health care professionals other than physicians or APPs may be better situated to provide options counseling to pregnant patients in some circumstances.<sup>160</sup>

71. The Rule bans any speech that could be interpreted to “promote” or “support abortion as a method of family planning,” as well as any speech during counseling or in

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<sup>155</sup> *Id.* at 7,789.

<sup>156</sup> *Id.* at 7,787, 7,789.

<sup>157</sup> *Id.* at 7,787.

<sup>158</sup> *Id.* at 7,716.

<sup>159</sup> Wynia Decl. ¶ 24.

<sup>160</sup> Kieltyka Decl. ¶¶ 34-37; Jenkins Decl. ¶¶ 8-9; NP Decl. ¶ 5.

connection with the permitted list of “comprehensive primary health care providers” that could be interpreted “as an indirect means of encouraging or promoting abortion as a method of family planning.”<sup>161</sup> The Rule does not define these terms or provide guidance as to how a doctor or APP may explain the availability of abortion to a patient in a manner that would not be interpreted as a violation.<sup>162</sup> Rather, the Rule states that “[t]he Department anticipates that it may provide further guidance to grantees on this issue,” but does not provide any timeline or expected likelihood with respect to such guidance.<sup>163</sup>

72. The Rule also prevents Title X clinics from making available to their patients any materials, written, video, web-based or otherwise, that mention abortion, even if no Title X funds are involved in providing the materials.<sup>164</sup>

**C. Physical Separation Requirements**

73. The Rule requires that Title X activities be “physically and financially separate” (defined as having an “objective integrity and independence”) from prohibited activities including the provision of abortion services.<sup>165</sup> The Rule gives the Secretary of HHS discretion to determine whether there is a violation of the physical separation requirements based on a “review of facts and circumstances.”<sup>166</sup>

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<sup>161</sup> Final Rule, 84 Fed. Reg. at 7,788-89.

<sup>162</sup> *Id.*

<sup>163</sup> *Id.* at 7,746.

<sup>164</sup> *Id.* at 7,790.

<sup>165</sup> *Id.* at 7,789; Hill Decl. ¶ 32.

<sup>166</sup> Final Rule, 84 Fed. Reg. at 7,789.

74. The Rule enumerates a non-exclusive list of factors the Secretary must consider as part of the review, including:

(a) The existence of separate, accurate accounting records; (b) The degree of separation from facilities (*e.g.*, treatment, consultation, examination and waiting rooms, office entrances and exits, shared phone numbers, email addresses, educational services, and websites) in which prohibited activities occur and the extent of such prohibited activities; (c) The existence of separate personnel, electronic or paper-based health care records, and workstations; and (d) The extent to which signs and other forms of identification of the Title X project are present, and signs and material referencing or promoting abortion are absent.<sup>167</sup>

75. The Rule’s preamble notes that physical separation at a “free-standing clinic,” like MFP, “might require more circumstances to be taken into account in order to satisfy a clear separation between Title X services and abortion services” because having the “same entrances, waiting rooms, signage, examination rooms, and the close proximity between Title X and impermissible services” presents “greater opportunities for confusion” than at a hospital.<sup>168</sup>

## **V. Defendants’ Analysis of the Rule’s Costs and Benefits**

### **A. Costs and Benefits of the Separation Requirements**

76. The Rule states that its physical separation requirements are justified in order to protect against “the intentional or unintentional co-mingling of Title X resources with non-Title X resources or programs.”<sup>169</sup>

77. Title X providers are already subject to regular and extensive compliance review by HHS to ensure federal funds are not used for prohibited activities. According to OPA, “family planning projects that receive Title X funds are closely monitored to ensure that federal

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<sup>167</sup> *Id.*

<sup>168</sup> *Id.* at 7,767.

<sup>169</sup> *Id.* at 7,715, 7,725.

funds are used appropriately and that funds are not used for prohibited activities such as abortion.”<sup>170</sup>

78. The Rule does not identify any misuse of Title X funds or any other Title X violations relating to colocation of services or otherwise.<sup>171</sup>

79. Instead, the Rule states that there is “potential for confusion” without the physical separation requirements,<sup>172</sup> and cites examples of abuse in other federal programs as support for Defendants’ view that there is a need for clarity.<sup>173</sup>

80. The Rule asserts that the costs of the physical separation requirements will be \$36.08 million nationwide, or between \$20,000 and \$40,000 per site.<sup>174</sup> The Rule does not provide evidence in support of those estimates.<sup>175</sup>

81. By contrast, numerous commenters cited evidence that the costs will substantially exceed that amount per site.<sup>176</sup> For example, Jodi Tomlonovic, the Executive Director of the Family Planning Council of Iowa, noted that “it typically costs hundreds of thousands, or even millions, of dollars to locate and open any health care facility (and would also cost much more than \$10-30,000 to establish even an extremely simple and limited office), staff it, purchase

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<sup>170</sup> ANGELA NAPILI, 2017 CRS REPORT 22, *supra* note 60.

<sup>171</sup> See Final Rule, 84 Fed. Reg. at 7,725; Proposed Rule, 83 Fed. Reg. at 25,509-10.

<sup>172</sup> Final Rule, 84 Fed. Reg. at 7,725.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at 7,781-82.

<sup>175</sup> *Id.*

<sup>176</sup> See, e.g., N.Y. Dep’t of Health Attachment to N.Y. Letter, *supra* note 100, at AR 239337-239338; Bailey Decl. ¶¶ 61-63; see also Hill Decl. ¶¶ 40-45.

separate workstations, set up record-keeping systems, etc.”<sup>177</sup> The New York Department of Health highlighted the hundreds of thousands of dollars in electronic records costs and thousands of dollars annually in duplicative administrative costs.<sup>178</sup> Planned Parenthood stated that “building and renovation costs alone would total \$1.2 billion in the first year after the regulation is finalized. This comes to an average cost of nearly \$625,000 per affected service site.”<sup>179</sup>

82. The Rule does not address impacts that the physical separation requirements will have on patients; for example, the Rule does not discuss that requiring physical separation of family planning services and abortion will disrupt the continuity of care as to patients for whom abortion is part of their comprehensive reproductive health care.<sup>180</sup> Evidence indicates that continuity between family planning and post-conception care enables improved patient-provider relationships and results in improved clinical outcomes.<sup>181</sup> Continuity of care reduces unnecessary testing, and potential for miscommunication.<sup>182</sup> It results in higher rates of preventive care, better record-keeping, and increased patient trust and satisfaction with their health care providers.<sup>183</sup>

83. As detailed *infra* in paragraphs 109-122, the Rule does not address the evidence presented that many providers would be forced out of the Title X program as a result of the

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<sup>177</sup> Family Planning Council of Iowa Letter, AR 279351.

<sup>178</sup> N.Y. Dep’t of Health Attachment to N.Y. Letter, *supra* note 100, at AR 239337-239338.

<sup>179</sup> PPAF Letter, *supra* note 103, at AR 316430-316431.

<sup>180</sup> N.Y. Dep’t of Health Attachment to N.Y. Letter, *supra* note 100, at AR 239320-239321; Bailey Decl. ¶ 107.

<sup>181</sup> N.Y. Letter, *supra* note 100, at AR 239318-239319.

<sup>182</sup> *Id.*

<sup>183</sup> *Id.*

physical separation requirements, and that the result would be a significant reduction in family planning services.

84. For example, Comments from the Institute for Policy Integrity at NYU Law School stated that “the end result” of the physical separation requirements “is that some women will lose access to some critical health care services, and that loss of access will result in a number of very real health, financial, physical, and psychological consequences for women and their families.”<sup>184</sup>

85. The comments further noted that the Rule will increase women’s transaction costs for receiving care, along with indirect social and economic costs for women.<sup>185</sup>

86. The Attorneys General of multiple states highlighted that “[a] recent report from the United Nations highlighted that placing barriers for low-income women to access health care ‘traps many women in cycles of poverty.’”<sup>186</sup>

**B. Costs and Benefits of the Gag Rule**

87. The Rule does not offer any evidence that the Gag Rule will provide benefits to patients receiving Title X care.<sup>187</sup>

88. Rather, the asserted basis for the Gag Rule is “maintaining the integrity of the Title X program.”<sup>188</sup>

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<sup>184</sup> Institute for Policy Integrity at NYU School of Law [hereinafter “Institute for Policy Integrity Letter”], AR 308568

<sup>185</sup> *Id.*

<sup>186</sup> Letter from Attorneys General of California, Connecticut, Delaware, Hawaii, Illinois, Iowa, Maine, Maryland, Minnesota, New Jersey, New Mexico, North Carolina, [hereinafter “Becerra Letter”], AR 245688.

<sup>187</sup> *See* Final Rule, 84 Fed. Reg. at 7,724.

<sup>188</sup> *Id.*

89. Defendants concluded that “the [R]ule adequately accommodates medical professionals and their ethical obligations.”<sup>189</sup> However, many commenters provided information in support of a finding that the Gag Rule interferes with the patient-provider relationship, results in worse health care for patients,<sup>190</sup> and that it forces providers to act and speak contrary to their medical judgment, their ethical obligations, and the standard of care.<sup>191</sup>

90. For example, ACOG, representing more than 4.3 million healthcare providers, explained that “[t]hese provisions represent an improper intrusion into the patient-physician relationship, the importance of which is underscored in the preamble of the Proposed Rule. . . . The result of such a regulation would be to mislead patients and delay their access to abortion care, placing providers in ethically compromised positions.”<sup>192</sup> ACOG further stated that “[t]he Proposed Rule’s restrictions on counseling and referral for abortion are a violation of the patient-physician relationship, undermine the quality of care provided to patients, place physicians in ethically compromising situations, and, accordingly, should not be implemented.”<sup>193</sup> And ACOG

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<sup>189</sup> *Id.*

<sup>190</sup> *See, e.g.*, Press Release, Am. Coll. of Obstetricians & Gynecologists, The Final Title X Regulation Disregards Expert Opinion and Evidence-Based Practices (Feb. 26, 2019), <https://www.acog.org/About-ACOG/News-Room/Statements/2019/Final-Title-X-Regulation-Disregards-Expert-Opinion-and-Evidence-Based-Practices?> [hereinafter “ACOG Press Release”]; AMA Letter, *supra* note 95, at AR 269332; ACOG Letter, *supra* note 95, at AR 268840; AAFP Letter, *supra* note 95, AR 104075; AAN Letter, *supra* note 95, at AR 107973.

<sup>191</sup> *See, e.g.*, AMA Letter, *supra* note 95, at 269332; ACOG Letter, *supra* note 95, at AR 268840; AAFP Letter, *supra* note 95, AR 104075; AAN Letter, *supra* note 95, at AR 107973.

<sup>192</sup> ACOG Letter, *supra* note 95, at AR 268840.

<sup>193</sup> *Id.*

concluded that the Rule “will do indelible harm to the health of Americans and to the relationship between patients and their providers.”<sup>194</sup>

91. The AMA concluded that “[t]he inability to . . . provide any and all appropriate referrals, including for abortion services, [is] contrary to the AMA’s Code of Medical Ethics.”<sup>195</sup>

92. The AAFP stated that “[t]he proposed rule would force health care providers to omit important and accurate medical information necessary for patients to make timely, fully informed decisions, encroaching upon physicians’ codes of ethics and responsibilities to patients.”<sup>196</sup>

93. The AAN explained that “[t]hese ethical obligations [in the Code of Ethics for Nurses] recognize that a patient’s informed consent and access to medically appropriate care is dependent upon both having all treatment options presented and referrals to appropriate providers.”<sup>197</sup>

94. As was pointed out in the comments, the ethics codes of leading medical associations also address this issue. The AMA states in its code of ethics that “[p]atients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communications in the patient-physician relationship foster trust and support shared decision making,”<sup>198</sup> and “[p]atients should be able to

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<sup>194</sup> ACOG Press Release, *supra* note 190; *see also* AMA Letter, *supra* note 95, at AR 269332; ACOG Letter, *supra* note 95, at AR 268840; AAFP Letter, *supra* note 95, AR 104075; AAN Letter, *supra* note 95, at AR 107973.

<sup>195</sup> AMA Letter, *supra* note 95, at AR 269332.

<sup>196</sup> AAFP Letter, *supra* note 95, AR 104075.

<sup>197</sup> AAN Letter, *supra* note 95, at AR 107973.

<sup>198</sup> AM. MED. ASSOC., CODE OF MEDICAL ETHICS § 2.1.1 INFORMED CONSENT, <https://www.ama-assn.org/delivering-care/informed-consent>; *see also* AMA Letter, *supra* note 95, AR 269330.

expect that their physicians will provide guidance about what they consider the optimal course of action for the patient based on the physician’s objective professional judgment.”<sup>199</sup> The AMA’s code of ethics further states that “withholding information without the patient’s knowledge or consent is ethically unacceptable.”<sup>200</sup>

95. ACOG’s code of professional ethics highlights the importance of the patient-physician relationship, noting “[t]he respect for the right of individual patients to make their own choices about their healthcare.”<sup>201</sup> ACOG’s policy statement on abortion notes that “[i]nduced abortion is an essential component of women’s health care.”<sup>202</sup>

96. The code of ethics for the American College of Nurse-Midwives states that midwives will “[d]evelop a partnership with the woman, in which each shares relevant information that leads to informed decision-making” and notes in a position statement that “everyone has the right to access factual, evidence-based, unbiased information about available [sexual and reproductive health] care services in order to make informed decisions.”<sup>203</sup> The American College of Nurse-Midwives further has stated that “[t]he proposed changes to the Title

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<sup>199</sup> AM. MED. ASSOC., CODE OF MEDICAL ETHICS OPINIONS § 1.1.3 PATIENT RIGHTS, <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-1.pdf> (emphasis added).

<sup>200</sup> AM. MED. ASSOC., CODE OF MEDICAL ETHICS OPINIONS § 2.1.3 WITHHOLDING INFORMATION FROM PATIENTS, <https://www.ama-assn.org/delivering-care/withholding-information-patients>.

<sup>201</sup> AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, CODE OF PROFESSIONAL ETHICS 1 (2018), <https://www.acog.org/-/media/Departments/National-Officer-Nominations-Process/ACOGcode.pdf?dmc=1&ts=20180726T1911469633>; *see also* ACOG Letter, *supra* note 95, at AR 268841.

<sup>202</sup> AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COLLEGE STATEMENT OF POLICY, ABORTION POLICY 1 (2014), <https://www.acog.org/-/media/Statements-of-Policy/Public/sop069.pdf?dmc=1&ts=20180726T1910257757>.

<sup>203</sup> AM. COLL. OF NURSE MIDWIVES, CODE OF ETHICS (2013), <http://www.midwife.org/ACNM/files/ACNMLibraryData/UPLOADFILENAME/000000000048/Code-of-Ethics.pdf>; AM. COLL. OF NURSE-MIDWIVES, POSITION STATEMENT: ACCESS TO COMPREHENSIVE SEXUAL AND REPRODUCTIVE HEALTH CARE SERVS. 1 (2016), <http://www.midwife.org/acnm/files/ACNMLibraryData/UPLOADFILENAME/000000000087/Access-to-Comprehensive-Sexual-and-Reproductive-Health-Care-Services-FINAL-04-12-17.pdf>.

X program would interfere with the provider-patient relationship by barring providers from providing critical reproductive-health information that midwives and other health care providers have a moral and ethical obligation to provide.”<sup>204</sup>

97. The American Nurses Association code of ethics states, “[p]atients have the moral and legal right to determine what will be done with and to their own person; to be given accurate, complete, and understandable information in a manner that facilitates an informed decision.”<sup>205</sup>

98. The Rule does not directly or substantively address any of the submitted comments asserting that the Gag Rule is incompatible with health care professionals’ ethics obligations and the standard of care, noting only that Defendants “disagree[.]”<sup>206</sup>

99. The Rule also disrupts the HHS-issued national standards of care (known as the “QFP”): the QFP was prepared by a team of experts within HHS and its sub-agencies (CDC and OPA) in 2014, was backed by extensive research, and was fully reaffirmed in December 2017.<sup>207</sup> The QFP requires “client-centered” care, which for pregnant patients includes nondirective “[o]ptions counseling” with “appropriate referrals.”<sup>208</sup> The QFP discusses pregnancy testing, nondirective counseling, and referrals under the heading “Pregnancy Testing and

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<sup>204</sup> American College of Nurse-Midwives Letter, AR 315935.

<sup>205</sup> AM. NURSES ASS’N, CODE OF ETHICS FOR NURSES WITH INTERPRETIVE STATEMENTS § 1.4 (2015), <https://www.nursingworld.org/coe-view-only>.

<sup>206</sup> Final Rule, 84 Fed. Reg. at 7,724.

<sup>207</sup> CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVS., PROVIDING QUALITY FAMILY PLANNING SERVICES [hereinafter “QFP”] (Apr. 24, 2014), <https://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf> (updating recommendations for 2017) (updated version available at <https://www.cdc.gov/mmwr/volumes/66/wr/mm6650a4.htm>).

<sup>208</sup> *Id.* at 2, 4, 13-14; Wynia Decl. ¶ 14.

Counseling.”<sup>209</sup> And the QFP also emphasizes that pregnancy “[o]ptions counseling should be provided in accordance with the recommendations from professional medical associations, such as ACOG and AAP.”<sup>210</sup>

100. As demonstrated by the comments detailed *supra* in paragraphs 87-99, and the testimony of a medical ethics expert, the ability to provide accurate, complete, and evidence-based information is a central component of the patient-provider relationship.<sup>211</sup>

101. Nondirective counseling, as that term is understood by experts in the field of medical ethics, enables a patient to choose between the medical options in line with their individual circumstances.<sup>212</sup> Under the Gag Rule, many patients will no longer be able to receive comprehensive reproductive health care information, including counseling about all their pregnancy options and referrals for an abortion provider where indicated, from their regular provider.<sup>213</sup>

102. Many patients who visit Title X–funded health centers do not know where the funding for their services comes from, much less that they are seeing a Title X–funded provider or even what Title X is.<sup>214</sup> Patients come to their health center with an expectation that they will

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<sup>209</sup> QFP, *supra* note 205, at 13-14.

<sup>210</sup> *Id.*

<sup>211</sup> Wynia Decl. ¶¶ 16-17; NP Decl. ¶ 18-19.

<sup>212</sup> Wynia Decl. ¶¶ 16-17; NP Decl. ¶¶ 15, 19; Jenkins Decl. ¶¶ 17-21.

<sup>213</sup> Bailey Decl. ¶ 49; Wynia Decl. ¶ 23; Jenkins Decl. ¶¶ 13-15; NP Decl. ¶ 18-19.

<sup>214</sup> NP Decl. ¶ 19; Jenkins Decl. ¶¶ 13-15.

receive a range of services, and that they will receive the full spectrum of information that is to be expected from candid conversations between health professionals and their patients.<sup>215</sup>

103. Under the Rule, some patients seeking abortion referrals will be confused and frustrated by their providers' unwillingness to provide information about abortion, thereby further eroding their patient-provider relationship.<sup>216</sup> Other patients may be misled by their providers' insistence on giving them information about prenatal care and adoption contrary to their expressed needs and preferences, and may interpret their providers' insistence on providing this information as disapproval of the patient's stated choice to have an abortion.<sup>217</sup>

104. Because a majority of women (around 60%) who use Title X–supported health care centers report that it is their usual source of medical care, those patients do not have an alternate source from which to get comprehensive information about their reproductive healthcare options from a medical professional.<sup>218</sup>

105. The Rule states that “[i]nformation about abortion and abortion providers is widely available and easily accessible, including on the internet.”<sup>219</sup> Commenters submitted evidence demonstrating that patients lack “knowledge and ability to navigate the health care system” and/or lack “regular access to communication tools (e.g., internet, phone) that are needed to access and research” this information,<sup>220</sup> and that patients with low health literacy may

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<sup>215</sup> Jenkins Decl. ¶¶ 17-21; NP Decl. ¶ 19; Bailey Decl. ¶¶ 46-50.

<sup>216</sup> Wynia Decl. ¶¶ 29-30; Kieltyka Decl. ¶ 37.

<sup>217</sup> Wynia Decl. ¶ 25; Jenkins Decl. ¶¶ 17-21; NP Decl. ¶ 18-19.

<sup>218</sup> Bailey Decl. ¶ 27 & n.39

<sup>219</sup> Final Rule, 84 Fed. Reg. at 7,746.

<sup>220</sup> RyanHealth Letter, AR 280324.

not be able to identify an appropriate health care provider after being given a general list that does not indicate which ones offer specific service sought.<sup>221</sup>

106. To the extent some related information is available on the Internet, the unsubstantiated and unvetted information on the Internet is not comparable to information and counseling patients receive from a qualified health care provider, which must be provided in accordance with the governing standard of care.<sup>222</sup> Moreover, much of the publicly-available information about abortion is misleading or medically inaccurate.<sup>223</sup> Information from other healthcare providers can also be inaccurate.<sup>224</sup>

107. Without referral support from Title X providers, patients seeking abortions must independently research whether any abortion providers offering care at the gestational stages needed by the patient are located nearby.<sup>225</sup> As part of that research, the patient may then have to contact or visit several providers in order to find one providing the care she seeks.<sup>226</sup>

108. These hurdles will delay affected patients' ability to access abortion care, and exacerbate the existing burdens patients with low incomes already face in accessing care, without any medical benefit.<sup>227</sup> For most patients with low incomes, visiting even one health care provider on the referral list who does not provide abortion care, and then taking time off to

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<sup>221</sup> Massachusetts League of Community Health Centers Letter, AR 283650.

<sup>222</sup> Wynia Decl. ¶¶ 23-31; NP Decl. ¶ 19.

<sup>223</sup> Jenkins Decl. ¶¶ 14-16; NP Decl. ¶¶ 16, 19; Kieltyka Decl. ¶ 30.

<sup>224</sup> Jenkins Decl. ¶¶ 14-16; NP Decl. ¶¶ 16, 19; Kieltyka Decl. ¶ 30.

<sup>225</sup> Wynia Decl. ¶¶ 31-32.

<sup>226</sup> NP Decl. ¶ 16; Jenkins Decl. ¶¶ 14-16.

<sup>227</sup> See *supra* notes 190-210; Wynia ¶¶ 31-32; Lindo Decl. ¶¶ 60-68; Bailey Decl. ¶¶ 122-29.

actually obtain an abortion, would mean multiple days of missed wages, and may even lead to job loss.<sup>228</sup>

**C. Costs Associated with Forcing Providers Out of the Title X Program**

109. The preamble to the Rule assumed that there would be no material reduction in Title X–funded family planning services as a result of the Rule.<sup>229</sup> The Rule states that “the Department cannot calculate or anticipate future turnover in grantees” and that such calculations would be “purely speculative” because “[v]arious entities may change their decision to apply to be a grantee or sub-grantees.”<sup>230</sup>

110. However, the administrative record contains evidence that there would be significant reductions in services as a result of the Rule.<sup>231</sup> For example, HHS was informed through comments that many grantees would exit the Title X program if the Rule went into effect, including Planned Parenthood, and at least four states—Hawaii, New York, Oregon, and Washington.<sup>232</sup>

111. The administrative record contains evidence that the Rule will decrease the number of family planning clinics overall, increase wait times, and decrease the use of effective

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<sup>228</sup> Lindo Decl. ¶¶ 57-77; Kieltyka Decl. ¶ 24-25.

<sup>229</sup> Final Rule, 84 Fed. Reg. at 7,723, 7,749, 7,782

<sup>230</sup> *Id.* at 7,782.

<sup>231</sup> *See, e.g.*, Institute for Policy Integrity Letter, *supra* note 184.

<sup>232</sup> *See, e.g.*, PPAF Letter, *supra* note 103, AR 316400; Letter from David Y. Ige, Governor, State of Hawaii, AR 305179; N.Y. Letter, *supra* note 100, AR 239318; Press Release, Kate Brown, Governor, State of Or., Governor Brown on Federal Title X Rollbacks on Access to Reproductive Health (July 30, 2018); Press Release, Jay Inslee, Governor, State of Wash., Protecting Washington Women from Trump Gag Rule (July 30, 2018).

contraceptive methods.<sup>233</sup> The Institute for Policy Integrity noted that “[t]he Proposed Rule is likely to reduce the availability and consumption of medical services.”<sup>234</sup>

112. Additional evidence indicated that new family planning providers, whether those are FQHCs or faith-based organizations, would not be able to replace Title X providers who exit the program in either quantity or quality of needed services.<sup>235</sup>

113. States submitted comments explaining how the resulting reduction in Title X clinics would increase travel distances for patients, and in many areas leave patients with no other option for obtaining family planning services.<sup>236</sup> For example, FQHCs and rural health centers in Vermont would be unable to absorb the needs of all Title X patients if the current Title X clinics became ineligible for Title X funds.<sup>237</sup> And in 33% of U.S. counties, there is no FQHC site providing contraceptive services, meaning women living there could lose access to Title X–supported services altogether.<sup>238</sup>

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<sup>233</sup> See, e.g., Institute for Policy Integrity Letter, *supra* note 184, at AR 308572; Guttmacher Letter, *supra* note 104, at AR 264433; PPAF Letter, *supra* note 103, AR 316400.

<sup>234</sup> Institute for Policy Integrity Letter, *supra* note 184, at AR 308572.

<sup>235</sup> Becerra Letter, *supra* note 186, at AR 245701; Letter from Attorneys General of Washington, Massachusetts, Oregon, & Vermont [hereinafter “Ferguson Letter”], AR 278551; Bailey Decl. ¶¶ 86-98.

<sup>236</sup> See Ferguson Letter, *supra* note 235, at AR 278574; Guttmacher Letter, *supra* note 104, at AR 264428; AAN Letter, *supra* note 95, at AR 107972 (citing Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women’s Health Program*, 374 NEW ENG. J. MED. 853 (2016)); see also Members of the House Letter, *supra* note 99, at AR 218728 (quoting Janet M. Bronstein, *Radical Changes for Reproductive Health Care—Proposed Regulations for Title X*, 379 NEW ENG. J. MED. 706 (2018)); PPAF Letter, *supra* note 103, AR 316400 (citing *Unintended Pregnancies and Abortions Averted by Planned Parenthood, 2015*, GUTTMACHER INST. (June 13, 2017), <https://www.guttmacher.org/infographic/2017/unintended-pregnancies-and-abortions-averted-planned-parenthood-2015>); ACLU Letter, *supra* note 105, at AR 305723.

<sup>237</sup> Ferguson Letter, *supra* note 235, at AR 278574.

<sup>238</sup> Guttmacher Letter, *supra* note 104, at AR 264428.

114. Members of the House noted that “the consequent changes in the Title X system are likely to increase unintended-pregnancy rates in the most vulnerable segments of the population and are thus more likely to increase than to reduce the incidence of abortions.”<sup>239</sup> In 2015, the Guttmacher Institute estimated that “Planned Parenthood’s provision of contraceptive services averted 430,000 unintended pregnancies.”<sup>240</sup> The ACLU noted that “[t]he proposed rule’s disruptions to the nation’s Title X network and prohibitions on standard medical care would lead to more unintended pregnancies.”<sup>241</sup>

115. Washington, a state with many rural areas, informed HHS that the Rule’s physical separation requirement and other provisions would leave over half of the state’s counties without a Title X provider.<sup>242</sup>

116. The Rule does not refute that clinics would leave the Title X program upon the Rule taking effect; instead, the Rule states that “new providers who previously were unable to participate in Title X projects due to conscience concerns” would apply to and participate in a Title X project because of the Rule’s changes to the nondirective pregnancy counseling provisions.<sup>243</sup> Defendants cited no evidence in support of that conclusion, nor any evidence that

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<sup>239</sup> Members of the House Letter, *supra* note 99, at AR 218728 (internal quotation marks omitted) (quoting Janet M. Bronstein, *Radical Changes for Reproductive Health Care—Proposed Regulations for Title X*, 379 NEW ENG. J. MED. 706 (2018)).

<sup>240</sup> PPAF Letter, *supra* note 103, at AR 316417 (citing *Unintended Pregnancies and Abortions Averted by Planned Parenthood, 2015*, GUTTMACHER INST. (June 13, 2017), <https://www.guttmacher.org/infographic/2017/unintended-pregnancies-and-abortions-averted-planned-parenthood-2015>)).

<sup>241</sup> ACLU Letter, *supra* note 105, at AR 305723.

<sup>242</sup> Ferguson Letter, *supra* note 235, at AR 278574.

<sup>243</sup> Final Rule, 84 Fed. Reg. at 7,719, 7,723, 7,782.

such new providers could or would fill the gap left open by providers who would leave the Title X program as a result of the Rule.<sup>244</sup>

117. The Rule states that HHS was unaware of “actual data that could demonstrate a causal connection between the type of changes to Title X regulations contemplated in this rulemaking and an increase in unintended pregnancies, births, or costs.”<sup>245</sup>

118. Commenters had explained that the loss of Planned Parenthood alone from the Title X program is likely to lead to a “decline in the use of the most effective methods of birth control and an increase in births among women who previously used long-acting reversible contraception.”<sup>246</sup>

119. Evidence from similar state-level legislation barring abortion-affiliated providers from participating in family planning programs demonstrates that the quantity and quality of family planning services likewise would decrease as a result of the Rule.<sup>247</sup> For example, after the Texas legislature passed multiple measures aimed at defunding Planned Parenthood affiliates, 40% of the state’s specialized family planning clinics closed, along with 19% of other family planning providers.<sup>248</sup> Service hours were reduced at many clinics, leading to longer waiting

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<sup>244</sup> *Id.*

<sup>245</sup> *Id.* at 7,775.

<sup>246</sup> AAN Letter, *supra* note 95, at AR 107972 (citing Amanda J. Stevenson et al., *Effect of Removal of Planned Parenthood from the Texas Women’s Health Program*, 374 *New Eng. J. Med.* 853 (2016)); *see also* Members of the House Letter, *supra* note 97, at AR 388364 (“[T]he consequent changes in the Title X system are likely to increase unintended-pregnancy rates in the most vulnerable segments of the population and are thus more likely to increase than to reduce the incidence of abortions.” (internal quotation marks omitted) (quoting Janet M. Bronstein, *Radical Changes for Reproductive Health Care—Proposed Regulations for Title X*, 379 *New Eng. J. Med.* 706 (2018)))

<sup>247</sup> Bailey Decl. ¶¶ 69-85, 94.

<sup>248</sup> *Id.* ¶ 72.

times for patients.<sup>249</sup> Organizations struggled to provide patients with the full range of contraceptive methods and saw reductions in the contraceptive methods they offered.<sup>250</sup> 28% of state-funded family planning clinics in the Rio Grande Valley closed, and many others had to raise fees.<sup>251</sup>

120. Similarly, the Iowa legislature voted in 2017 to exclude from Iowa's state-funded family planning program agencies that also provided abortion or operated a facility where abortions were performed.<sup>252</sup> As a result, the number of patients enrolled in the program fell by half and services provided declined by 73%—despite there being \$2.5 million remaining in the program that was not spent.<sup>253</sup>

121. Once clinics are forced to close, financial and other barriers involved in reopening them are often insurmountable.<sup>254</sup> Following the implementation of House Bill 2 in Texas, the law declared unconstitutional by the Supreme Court in *Whole Woman's Health v. Hellerstedt*, 20 Texas clinics closed.<sup>255</sup> As of 2017, only two of those clinics had been able to reopen.<sup>256</sup>

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<sup>249</sup> *Id.* ¶ 73.

<sup>250</sup> *Id.* ¶ 76.

<sup>251</sup> *Id.* ¶ 79.

<sup>252</sup> *Id.* ¶ 81.

<sup>253</sup> *Id.* ¶ 82.

<sup>254</sup> See N. MADSEN ET AL., ABORTION CARE NETWORK, COMMUNITIES NEED CLINICS: THE ROLE OF INDEPENDENT ABORTION CARE PROVIDERS IN ENSURING MEANINGFUL ACCESS TO ABORTION CARE IN THE UNITED STATES 8 (2017), <https://www.abortioncarenetwork.org/wp-content/uploads/2017/08/CommunitiesNeedClinics2017.pdf>.

<sup>255</sup> *Id.* at 8.

<sup>256</sup> *Id.*

122. The reduction in subsidized family planning access that accompanies clinic closures or reduction in services has long-lasting effects on women who use these programs and on their families.<sup>257</sup>

**D. HHS’s Implementation of the Rule and Its Aftermath Have Borne Out Costs and Concerns that Were Laid Out in Comments**

123. Commenters’ predictions regarding loss of access to Title X services have already been borne out, and the situation continues to worsen.<sup>258</sup> As predicted, Planned Parenthood, several states, and other entities, including MFP, have been forced to leave the program since the Rule went into effect.<sup>259</sup> In total, at least 18 of the 90 Title X grantees across the United States have been forced out of the Title X program as a result of the Rule to date, along with their subgrantees.<sup>260</sup> Additional subgrantees have left the program as well; in total, as of October 2019, more than 1000 clinics that had previously provided Title X–funded services were no longer using Title X funds, including all those in Hawaii, Vermont, Maine, Utah, Oregon, and Washington.<sup>261</sup> In particular, studies indicate that the withdrawal of Planned Parenthood—which served 40% of Title X’s patients—from the Title X program will create a surge of demand on

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<sup>257</sup> Bailey Decl. ¶¶ 122-131; Lindo Decl. ¶¶ 71-72.

<sup>258</sup> Brittni Fredriksen et al., Kaiser Family Foundation, *Data Note: Is the Supplemental Title X Funding Awarded by HHS Filling in the Gaps in the Program?* (Oct. 18, 2019) [hereinafter Fredriksen, *Supplemental Funding*], <https://www.kff.org/womens-health-policy/issue-brief/data-note-is-the-supplemental-title-x-funding-awarded-by-hhs-filling-in-the-gaps-in-the-program/>.

<sup>259</sup> Kinsey Hasstedt, *Beyond Rhetoric: The Real-World Impact of Attacks on Planned Parenthood and Title X*, 20 GUTTMACHER POL’Y REV. 86, 87 (2017) [hereinafter, Hasstedt, *Beyond Rhetoric*], <https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x>; Hill Decl. ¶ 19.

<sup>260</sup> Fredriksen, *Supplemental Funding*, *supra* note 258.

<sup>261</sup> Kaiser Family Foundation, *Status of Participation in the Title X Family Planning Program*, <https://www.kff.org/interactive/the-status-of-participation-in-the-title-x-federal-family-planning-program/>; Hill Decl. ¶ 19.

remaining comprehensive reproductive health care providers.<sup>262</sup> The most recent research shows that the Title X program's capacity has been reduced by at least 47% nationwide, and in six states—including Maine—there are no Title X services currently available.<sup>263</sup> And there are already anecdotal reports of clinics that withdrew from the program closing or raising prices from lack of funds.<sup>264</sup> No new awards to new grantees have been made since the Rule went into effect, and while HHS has released supplemental funding, that funding went to existing grantees with limited capacity and geographical reach.<sup>265</sup>

## **VI. Implementation of the Rule by MFP is Infeasible**

124. MFP currently offers abortion at all 18 of its directly-managed clinics, including medication abortion at its 17 satellite locations.<sup>266</sup>

125. Implementation of the physical separation requirements would force MFP to cease abortion-related activities at all 17 of its satellite clinics.<sup>267</sup> These sites are sufficiently small such that “separating” the sites will mean acquiring a separate building, rather than simply subdividing the space, and the cost of finding, building, and maintaining an additional 17

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<sup>262</sup> See generally Hasstedt, *Beyond Rhetoric* at 87, *supra* note 259.

<sup>263</sup> Bailey Decl. ¶ 89; Ruth Dawson, *Trump Administration's Domestic Gag Rule Has Slashed the Title X Network's Capacity by Half*, GUTTMACHER INSTITUTE (Feb. 5, 2020), <https://www.guttmacher.org/article/2020/02/trump-administrations-domestic-gag-rule-has-slashed-title-x-networks-capacity-half>.

<sup>264</sup> Bailey Decl. ¶ 89.

<sup>265</sup> *Id.*

<sup>266</sup> *Id.* ¶ 38 n.5; Jenkins Decl. ¶ 22; Kieltyka Decl. ¶¶ 16, 17.

<sup>267</sup> Hill Decl. ¶¶ 31-39

separate spaces is prohibitive.<sup>268</sup> There are no available providers in other states in close proximity to these 17 satellite locations—the nearest are in New Hampshire and Vermont.<sup>269</sup>

126. If MFP were to stop providing abortion at these 17 sites, women across Maine seeking to access abortion would be forced to travel significantly farther for that care: in the northwest part of the state, most women would have to travel an additional 25-50 miles, while in the southeast, they would have to travel an additional 75 miles.<sup>270</sup> While currently only 6.1% of MFP's satellite clinic patients have had to travel more than 25 miles to reach their nearest abortion provider, if MFP's satellite clinics close, 82.7% of those patients would have to travel more than 25 miles to reach their nearest clinic to have an abortion, and 15.1% of those patients would have to travel 100 miles or more.<sup>271</sup> If all Maine women of reproductive age whose closest abortion provider is one of MFP's satellite clinics are considered, only 7.9% currently live over 25 miles from an abortion provider, but that number would increase to 76.1%.<sup>272</sup>

127. Empirical evidence demonstrates that even relatively small increases in travel distances reduce rates of abortion significantly.<sup>273</sup>

128. Evidence shows that transportation barriers are significant challenges in accessing healthcare, especially for low-income people,<sup>274</sup> and that transportation barriers negatively

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<sup>268</sup> *Id.*

<sup>269</sup> Lindo Decl. ¶¶ 11, fig.1.

<sup>270</sup> *Id.* ¶¶ 11-12.

<sup>271</sup> *Id.* ¶¶ 14-17.

<sup>272</sup> *Id.* ¶ 16 tbl.2.

<sup>273</sup> Lindo Decl. ¶ 9; *see also* Bailey Decl. ¶ 98-100.

<sup>274</sup> Lindo Decl. ¶ 19-24; Bailey Decl. ¶¶ 98-107.

impact healthcare access.<sup>275</sup> Even small increased distances, such as 25 additional miles, prevent women from accessing abortion at all and delay many others.<sup>276</sup> Quantitative analyses performed in varying geographic and demographic regions suggest similar causal relationships, demonstrating that the reaction among women seeking abortion to even small increases in distance is likely to hold across a variety of different states, including in Maine.<sup>277</sup>

129. Traveling throughout Maine can be extremely time-consuming and difficult because there is only one north-south interstate highway; transportation within and among counties is limited; many people do not have a private vehicle; and there are few public transportation options outside of Portland.<sup>278</sup> Thus, traveling additional miles in Maine often takes far longer than it would in other places, and sometimes is impossible, particularly when it requires travel on local or country roads and/or during inclement weather.<sup>279</sup>

130. The majority of MFP's abortion patients routinely report that they do not have, and will not be able to find, the money they need to travel to a clinic in a different city for abortion care.<sup>280</sup> MFP's abortion patients often work in low-wage jobs that do not offer paid time off or sick leave and require unpredictable schedules as well struggle with the cost of childcare.<sup>281</sup>

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<sup>275</sup> Lindo Decl. ¶¶ 19-31.

<sup>276</sup> *Id.* ¶¶ 32-37.

<sup>277</sup> *Id.* ¶¶ 34-45.

<sup>278</sup> *Id.* ¶¶ 27-30; Jenkins Decl. ¶¶ 8-9, 23-26; NP Decl. ¶¶ 6-7.

<sup>279</sup> Lindo Decl. ¶¶ 9, 40-50; NP Decl. ¶¶ 6-7, 22, 25; Jenkins Decl. ¶¶ 8-9, 23-26.

<sup>280</sup> Kieltyka Decl. ¶ 24-25.

<sup>281</sup> *Id.*

131. The effects of the Rule will prevent some of MFP's patients from accessing abortion procedures altogether.<sup>282</sup> Economist Dr. Lindo estimates that, if MFP implements the Rule, the abortion rate in Maine will drop by 12-14%.<sup>283</sup>

132. The Gag Rule, by barring health care professionals from providing full and accurate information about abortion services and abortion referrals, would further impede some of MFP's patients' ability to timely access abortion care.<sup>284</sup> In practice, the Rule would require a patient's medical provider to rebuff questions about where to obtain an abortion even in the middle of an appointment or consultation, perhaps while the patient is partially disrobed or in the middle of being examined in some way.<sup>285</sup>

133. MFP's providers' experiences with patients demonstrate that information about abortion and abortion providers is not easily available or accessible to their patients without the assistance of a healthcare provider.<sup>286</sup> One reason for this, among other things, is that many of MFP's patients have difficulty accessing the Internet.<sup>287</sup> And in some areas of Maine, other local healthcare providers are not willing or able to openly discuss all options available to women who are pregnant, including abortion.<sup>288</sup> Moreover, much of the information that is otherwise

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<sup>282</sup> See Jenkins Decl. ¶¶ 24-26; NP Decl. ¶¶ 21-25.

<sup>283</sup> Lindo Decl. ¶¶ 9, 49-50.

<sup>284</sup> See Wynia Decl. ¶¶ 31-32; NP Decl. ¶¶ 15-16, 21-25; Kieltyka Decl. ¶¶ 32-34.

<sup>285</sup> See Jenkins Decl. ¶¶ 17-21; Kieltyka Decl. ¶¶ 31-35.

<sup>286</sup> Jenkins Decl. ¶ 14-16; NP Decl. ¶¶ 15-16, 19.

<sup>287</sup> NP Decl. ¶¶ 16-19.

<sup>288</sup> NP Decl. ¶ 16.

available to MFP's patients about abortion and abortion providers is unreliable and incorrect, sometimes to the point of being dangerous.<sup>289</sup>

134. For some Maine women who ultimately could find an abortion provider and make the extended trip, the costs and challenges of travel would still delay their care.<sup>290</sup>

135. Without abortion access at MFP's 17 satellite clinics, patients' options for scheduling this travel would be further complicated because the only three remaining abortion clinics that would provide abortion care do so only one day per week, which would inevitably lead to further delays.<sup>291</sup>

136. Delays in accessing abortion would harm MFP's patients in multiple ways: increases in travel distance increase costs due to childcare, lost wages, and transportation,<sup>292</sup> and delays cause patients to require incrementally more complex and expensive procedures.<sup>293</sup> On average, women whose procedure is delayed will face an increase of \$37, with a high end of \$111 for some women.<sup>294</sup> Once delays begin pushing women later in pregnancy, the costs increase, for some women, by hundreds of dollars.<sup>295</sup> A delay beyond 11 weeks LMP precludes a woman from receiving a medication abortion anywhere in Maine.<sup>296</sup> A delay through 14-16

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<sup>289</sup> Jenkins Decl. ¶ 14; NP Decl. ¶¶ 15-16; 19.

<sup>290</sup> Lindo Decl. ¶¶ 51-72; Jenkins Decl. ¶¶ 23-26; NP Decl. ¶ 25; Kieltyka Decl. ¶¶ 22-25.

<sup>291</sup> Kieltyka Decl. ¶¶ 22-25.

<sup>292</sup> Lindo Decl. ¶¶ 60-70; Kieltyka Decl. ¶¶ 24, 25.

<sup>293</sup> Lindo Decl. ¶¶ 60-63.

<sup>294</sup> *Id.* ¶ 58.

<sup>295</sup> *Id.* ¶¶ 61-63.

<sup>296</sup> *Id.* ¶ 60.

weeks LMP substantially increases the cost of the procedure by approximately \$100-\$400.<sup>297</sup> These costs increase even more substantially if a woman is pushed beyond 16 weeks LMP.<sup>298</sup> If a woman is pushed beyond 19 weeks LMP, she will be unable to have an abortion at a Maine clinic or in the clinics in nearby states.<sup>299</sup> While these costs might be inconvenient for a middle- or upper-income patient, research shows that such incremental increases in cost force low-income people, especially abortion patients, to forego meeting critical needs—sacrificing food, utilities, and rent—and risk women’s housing, job, and other hardships.<sup>300</sup>

137. Given the challenges faced by the majority low-income population served by MFP, in combination with Maine’s geography and level of poverty, the additional costs imposed on MFP’s patients by the loss of abortion services in the 17 satellite locations will reduce abortions and impose tremendous economic burdens.<sup>301</sup>

138. Delays in accessing abortion care lead to increased health risks for women.<sup>302</sup> While all abortion procedures are safe, the risks, costs, and complexity of abortion increase with gestational age.<sup>303</sup> Delays also will prevent some women from accessing their preferred, or medically-indicated, abortion procedure.<sup>304</sup> Some women, especially from rural areas, will be

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<sup>297</sup> *Id.* ¶ 61.

<sup>298</sup> *Id.* ¶ 62.

<sup>299</sup> *Id.* ¶ 63.

<sup>300</sup> *Id.* ¶ 66.

<sup>301</sup> *Id.* ¶¶ 26-30, 60-70; Kieltyka Decl. ¶¶ 22-24; NP Decl. ¶¶ 6-7, 22-25; Jenkins Decl. ¶¶ 23-26.

<sup>302</sup> Bailey Decl. ¶ 125.

<sup>303</sup> *Id.*

<sup>304</sup> Kieltyka Decl. ¶ 24; Jenkins Decl. ¶¶ 24-25; NP Decl. ¶ 23.

unable to travel to a clinic before its gestational limit and so will be prevented from accessing abortion care in Maine altogether.<sup>305</sup> When women are denied wanted abortions, they and their families experience a host of harms, including worsening poverty.<sup>306</sup>

139. Finally, it is not certain that MFP could implement the physical separation requirements at its headquarters clinic in Augusta.<sup>307</sup> Assuming *arguendo* that MFP were able to separate its abortion services and its Title X services at its Augusta headquarters, doing so would come at a price much higher than the Rule's estimated costs of \$20,000 to \$40,000.<sup>308</sup> MFP estimates that the Augusta building would, with an 800 square foot addition, accommodate separate family planning and abortion facilities with separate entrances.<sup>309</sup> The physical alterations to the space alone would cost, at a minimum, \$120,000-\$135,000.<sup>310</sup> If completely separate buildings are required, renting new clinical space to provide abortion services would cost over \$200,000 with much of that cost recurring every four years.<sup>311</sup> Building new space would cost between \$250,000 and \$400,000 without accounting for the price of land or cost of furnishing.<sup>312</sup>

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<sup>305</sup> Kieltyka Decl. ¶¶ 24; NP Decl. ¶¶ 26; Jenkins Decl. ¶¶ 8-9, 23-26.

<sup>306</sup> Lindo Decl. ¶ 71-72; Bailey Decl. ¶¶ 129-131.

<sup>307</sup> Hill Decl. ¶¶ 40-45.

<sup>308</sup> *Id.*

<sup>309</sup> *Id.*

<sup>310</sup> *Id.* ¶¶ 40-43.

<sup>311</sup> *Id.* ¶¶ 42.

<sup>312</sup> *Id.* ¶¶ 44.

## VII. Harm to Plaintiffs Upon the Rule's Enforcement

140. On January 10, 2019, MFP submitted a grant application for the three-year grant cycle to begin on April 1, 2019.<sup>313</sup> HHS had instructed Title X applicants, including MFP, to apply for that grant cycle based on the Title X regulations that were then currently in effect.<sup>314</sup> In reliance on HHS's instructions, MFP submitted its January 10 grant application for the next cycle in accordance with the regulations in effect at the time the application was due.<sup>315</sup> The January 10 grant application contemplated continuing to expand MFP's network of subrecipients by maintaining all current sites and contracting with a new FQHC in Washington County.<sup>316</sup>

141. On March 26, 2019, MFP was awarded a three-year grant for the April 1, 2019 to March 31, 2022 period.<sup>317</sup> The amount of the award was \$1,800,000 for year one, \$1,830,000 for year two, and \$1,860,000 for year three.<sup>318</sup>

142. After the Rule was issued on March 4, 2019, and while the 2019-2022 grant cycle was ongoing, MFP received a July 15, 2019 notification from Diane Foley of OPA that as of July 15, 2019, HHS would be requiring immediate compliance with all portions of the Rule other than

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<sup>313</sup> *Id.* ¶ 17.

<sup>314</sup> *Id.*

<sup>315</sup> *Id.*

<sup>316</sup> *Id.*

<sup>317</sup> *Id.*

<sup>318</sup> *Id.*

the physical separation requirements.<sup>319</sup> The physical separation requirements would still go into effect on the originally scheduled date of March 4, 2020.<sup>320</sup>

143. On August 19, 2019, MFP sent a letter to Diane Foley informing OPA that MFP was withdrawing from the Title X program after 47 years as the State of Maine's Title X grantee.<sup>321</sup> The letter stated that MFP had no choice but to withdraw from the program because the Rule would require its healthcare providers to withhold crucial information from the low-income population that relies on its family planning services and because the Rule conditions provision of abortion services on MFP adopting a physical structure that is both irrational and impossible for the organization to sustain.<sup>322</sup>

144. Because Title X funds had composed over 27% of MFP's annual budget, upon exiting the program, MFP had to rely on its limited reserves while attempting to make up for the resulting loss.<sup>323</sup> While private donors and foundations have stepped in to help MFP keep its doors open in the near term, such funding will not permanently fill the gap.<sup>324</sup>

145. Without Title X funds or equivalent private donations, which MFP has no expectation of receiving on an indefinite basis, MFP would be forced to cut back on a significant portion of its services, including closing clinics, downsizing staff, and eliminating some family

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<sup>319</sup> *Id.* ¶ 18.

<sup>320</sup> *Id.*

<sup>321</sup> *Id.* ¶ 19.

<sup>322</sup> *Id.*

<sup>323</sup> *Id.* ¶ 20.

<sup>324</sup> *Id.* ¶¶ 20, 21.

planning services altogether.<sup>325</sup> MFP is not aware of any organizations in Maine planning to apply to provide Title X–funded services, much less to fill the healthcare gap that would be left for the people in Maine if MFP is forced to cut back its services.<sup>326</sup>

146. As a result of leaving the program, MFP also has lost access to other resources on which it relied to support its provision of family planning services.<sup>327</sup> For example, MFP no longer has access to technical assistance from the National Family Planning Training Center, on which it had substantially relied to conduct training on topics like clinical flow and patient management, or to a regional consultant through OPA.<sup>328</sup> Title X training programs were an especially important resource for MFP because it is not large enough to maintain its own in-house training program.<sup>329</sup> MFP’s loss of Title X funds also has forced it to redirect its development efforts, in order to obtain funds that are necessary merely to maintain its core family planning programs.<sup>330</sup> As a result, MFP has had to forgo opportunities to fundraise for or otherwise develop other aspects of its practice and mission.<sup>331</sup>

**RESPONSE TO DEFENDANTS’ STATEMENT OF UNDISPUTED MATERIAL FACTS**

1. Congress enacted Title X of the Public Health Service Act in 1970. *See* Pub. L. No. 91-572, 84 Stat. 1504.

**Response:** Admitted.

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<sup>325</sup> *Id.* ¶ 21.

<sup>326</sup> *Id.*

<sup>327</sup> *Id.* ¶ 22.

<sup>328</sup> *Id.*

<sup>329</sup> *Id.*

<sup>330</sup> *Id.* ¶ 23.

<sup>331</sup> *Id.*

2. The Department of Health and Human Services (HHS) promulgated regulations on February 2, 1988 that, among other things, prohibited Title X projects from referring patients for abortion as a method of family planning and required Title X programs to be physically separate from abortion-related activities. 53 Fed. Reg. 2922 (Feb. 2, 1988).

**Response:** Qualified. Plaintiffs deny the characterizations in this paragraph to the extent its description of the regulations is incomplete and therefore inaccurate. Plaintiffs refer the Court to paragraphs 38-43 of their Statement of Undisputed Material facts *supra* for a more accurate and complete recitation of the relevant and material facts on this point. Alternatively, Plaintiffs refer the Court to the regulation itself, which is the best evidence of its content.<sup>332</sup>

3. The Supreme Court upheld these 1988 regulations against challenges brought under the APA and the Constitution. *See Rust v. Sullivan*, 500 U.S. 173 (1991).

**Response:** Qualified. Plaintiffs deny the characterizations in this paragraph to the extent its description of *Rust v. Sullivan* is incomplete and therefore inaccurate. Plaintiffs refer the Court to paragraphs 38-43 of their Statement of Undisputed Material Facts *supra* for a more accurate and complete recitation of the relevant and material facts on this point. Alternatively, Plaintiffs refer the Court to the case law itself, which is the best evidence of its content.<sup>333</sup>

4. Congress has not amended Title X since *Rust* was decided.

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<sup>332</sup> Statutory Prohibition on Use of Appropriated Funds In Programs Where Abortion Is a Method of Family Planning; Standard of Compliance for Family Planning Services Projects, 53 Fed. Reg. 2,922 (Feb. 2, 1988) (codified at 42 C.F.R. pt. 59).

<sup>333</sup> *See Rust v. Sullivan*, 500 U.S. 173 (1991).

**Response:** Qualified. Plaintiffs deny the characterizations in this paragraph to the extent they fail to account for additional requirements applicable to the Title X program following *Rust*. Plaintiffs refer the Court to paragraphs 25-40 of their Statement of Undisputed Material facts *supra* for a more accurate and complete recitation of the relevant and material facts on this point.<sup>334</sup>

5. The 1988 regulations were suspended in 1993. 58 Fed. Reg. 7455 (Jan. 22, 1993); 58 Fed. Reg. 7464 (Feb. 5, 1993).

**Response:** Admitted.

6. On July 3, 2000, HHS promulgated regulations that (1) required Title X projects to offer and provide upon request “information and counseling regarding” specific options, including “[p]regnancy termination,” followed by “referral upon request,” and (2) eliminated the physical-separation requirement from the 1988 regulations. 65 Fed. Reg. 41,270 (July 3, 2000).

**Response:** Qualified. Plaintiffs deny the characterizations in this paragraph to the extent its description of the regulations is incomplete and therefore inaccurate. Plaintiffs refer the Court to paragraphs 36 and 44 of their Statement of Undisputed Material facts *supra* for a more accurate and complete recitation of the relevant and material facts on this point. Alternatively, Plaintiffs refer the Court to the regulation itself, which is the best evidence of its content.<sup>335</sup>

7. On June 1, 2018, HHS issued a notice of proposed rulemaking (NPRM) relating to the Title X program. 83 Fed. Reg. 25,502 (June 1, 2018).

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<sup>334</sup> See, e.g., Continuing Appropriations Act, 2019, Pub. L. 115-245, 132 Stat. 2981, 3070-71 (2018) (nondirective counseling mandate).

<sup>335</sup> 2000 Rule, 65 Fed. Reg. 41,270.

**Response:** Admitted.

8. HHS received more than 500,000 comments on the NPRM, but none of the comments argued that the proposed rule would violate the “Access to therapies” provision of the Affordable Care Act, 42 U.S.C. § 18114.

**Response:** Qualified. While Plaintiffs are not aware of a comment on the Proposed Rule specifically citing Section 1554, numerous comments addressed its substantive prongs, for example, Plaintiffs refer the Court to paragraph 54 of their Statement of Undisputed Material Facts *supra* for comments describing “unreasonable barriers to care”; “impediments to timely care access”; “interference with communications regarding treatment option”; “restriction on full disclosure of all relevant information to patients”; and “violation of ethical standards of healthcare professionals.”<sup>336</sup>

9. On March 4, 2019, HHS promulgated a final rule that prohibits Title X projects from providing referrals for, or engaging in activities that otherwise encourage or promote, abortion as a method of family planning. 84 Fed. Reg. 7714 (Mar. 4, 2019) (Rule). The Rule also requires that Title X projects remain physically separate from any abortion-related activities conducted outside the program.

**Response:** Plaintiffs’ deny the characterizations in this paragraph to the extent its description of the regulations is incomplete and therefore inaccurate. Plaintiffs refer the Court to paragraphs 47-75 of their Statement of Undisputed Material facts *supra* for a

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<sup>336</sup> See, e.g., N.Y. Letter, *supra* note 100, at AR 239322 (describing unreasonable barriers to care); PPAF Letter, *supra* note 103, at AR 316430-316431 (describing impediments to timely care access); AMA Letter, *supra* note 95, at AR 269332 (describing interference with communications regarding treatment options); ACOG Letter, *supra* note 95, at 268840 (describing restriction on full disclosure of relevant information to patients); AAFP Letter, *supra* note 95, AR 104075 (describing violations of ethical standards of healthcare professionals).

more accurate and complete recitation of the relevant and material facts on this point.

Alternatively, Plaintiffs refer the Court to the regulation itself, which is the best evidence of its content.<sup>337</sup>

10. Plaintiffs filed a lawsuit under the APA challenging the Final Rule on March 6, 2019. ECF No. 1.

**Response:** Qualified. Plaintiffs admit that they filed a lawsuit challenging the Final Rule on March 6, 2019 and that the lawsuit raises claims pursuant to the APA. This request is denied to the extent that it is incomplete because Plaintiffs also bring independent constitutional claims, including an as-applied substantive due process claim, a First Amendment claim, and an Equal Protection claim.<sup>338</sup>

11. The basis for the Rule is set forth in the preamble to the Rule, located in the Federal Register at 84 Fed. Reg. 7714 and in the administrative record.

**Response:** Qualified. Plaintiffs admit that the Rule has a preamble that purports to state bases for the Rule. Plaintiffs otherwise deny the characterizations in this paragraph to the extent its description of the preamble is incomplete and therefore inaccurate. Plaintiffs' further deny the characterizations in this paragraph to the extent it suggests the bases stated in the preamble are true, complete, or legally sufficient to justify the Rule.

Plaintiffs refer the Court to paragraphs 76-122 of their Statement of Undisputed Material facts *supra* for a more accurate and complete recitation of the relevant and material facts

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<sup>337</sup> Final Rule, 84 Fed. Reg. 7,714.

<sup>338</sup> Am. Compl. ¶¶ 209-240.

on this point. Alternatively, Plaintiffs refer the Court to the Rule itself, including its preamble, which is the best evidence of its content.<sup>339</sup>

Dated: February 27, 2020

Respectfully submitted,

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<sup>339</sup> Final Rule, 84 Fed. Reg. 7,714.

**CERTIFICATE OF SERVICE**

I hereby certify that on the 27th day of February, 2020, I filed a copy of the above Motion with the Clerk of Court through the ECF system, which automatically sent a Notice of Electronic Filing to all counsel of record.

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