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VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G, Hubert H. Humphrey Building
Washington, D.C. 20201

Attn: CMS-9940-IFC
Religious Exemptions and Accommodations for
Coverage of Certain Preventive Services Under the
Affordable Care Act

Dear Acting Secretary Hargan:

The National Health Law Program (NHeLP) appreciates the opportunity to comment on the Interim Final Rule for Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act (hereafter “IFR”), from the Department of the Treasury, Department of Labor, and Department of Health and Human Services (“HHS”) (collectively “Departments”) published October 13, 2017.¹ NHeLP protects and advances the health rights of low-income and underserved individuals. Founded in 1969, NHeLP advocates, litigates, and educates at the federal and state levels. Consistent with this mission, NHeLP works to ensure that all people in the United States – including women – have access to comprehensive preventive health services, including contraception. NHeLP unequivocally opposes the Departments’ efforts to undermine the Affordable Care Act’s (“ACA”) contraceptive coverage requirement through this IFR.

I. Introduction

The ACA seeks to address the lack of adequate and affordable health insurance coverage—and to remedy inadequate access to health care. In line with this goal, the ACA recognizes that preventive health services are critical to individual and community health and that cost is a barrier to access. The ACA builds upon existing federal laws and increases access to preventive health care services by requiring most group health plans and health insurance issuers to cover, without cost-sharing, women’s preventive health care services identified in guidelines issued by the United States HHS’ Health Resources and Services Administration (“HRSA”).² These HRSA recommendations are based on an extensive evidence-based analysis by the Institutes of Medicine (IOM).³ These guidelines were updated in 2016 based on recommendations from the Women’s Preventive Services Initiative (WPSI) as part of a five-year cooperative agreement between the American College of Obstetricians and Gynecologists and HRSA to coordinate the development, review, and update of recommendations. These too were adopted by HRSA.⁴ The ACA’s requirements ensure that all individuals, regardless of where they work, have seamless access to all Food and Drug Administration (“FDA”)-approved methods of contraception without cost-sharing.

The IFR exempts all non-profit or for-profit employers (including publicly traded companies) and private institutions of higher education that issue student health plans from complying with the contraceptive care requirement of the ACA if these entities object on the basis of religious beliefs. In addition, the IFR gives exempted employers and institutions the authority to decide whether their employees and students receive independent contraceptive care coverage through the accommodation process. The expanded exemption applies only to the contraceptive care requirement.

We are very concerned that the IFR deprives individuals, particularly low-income women, of health care benefits that medical and health care experts recognize as critical to ensuring reproductive health and well-being. In broadly exempting universally all employers from contraceptive coverage policies, the IFR gravely threatens a person’s ability to determine the contraceptive method that best suits their needs, and when and if to become pregnant. The exemption undermines the ACA’s intention to ensure all women receive

¹ Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21851.pdf> (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).

² See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2713(a)(4), 124 Stat. 119, 131 (codified at 42 U.S.C. § 300gg-13(a)(4)); U.S. Dep’t of Health & Human Servs. (HHS), Health Res. & Servs. Admin., *Women’s Preventive Services: Required Health Plan Coverage Guidelines*, <https://www.hrsa.gov/womens-guidelines-2016/index.html> (last visited Nov. 2, 2017).

³ Inst. of Med. of the Nat’l Acads. (IOM), *Clinical Preventive Services for Women: Closing the Gaps* 19 (2011), <http://www.nationalacademies.org/hmd/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx>.

⁴ HHS, *Women’s Preventive Services*, *supra* note 2.

comprehensive coverage of the full range of FDA-approved, contraceptive drugs and devices.

II. The IFR Violates the Administrative Procedure Act

The Departments published this rule as an interim final rule, effective immediately upon publication. This violates the Administrative Procedure Act (“APA”). The APA requires an agency to follow notice and comment procedures unless the agency can establish good cause to skip that process. Good cause is narrowly construed and exists only where public comment is “impracticable, unnecessary, or contrary to the public interest.” Good cause does not exist here.

The Departments justify their haste in part by arguing that the public previously commented on related regulations and therefore has had an opportunity to engage. However, relying on comments submitted during prior comment periods on related regulations is insufficient to meet public notice requirements under the APA. The Departments further argue that the interim final rule is justified by a need to “provide immediate resolution” to a number of open legal challenges to the existing scheme. But the existence of litigation does not create urgency and certainly does not warrant ignoring basic requirements for broad public participation (even if a handful of employers and universities are advocating for the rule).

Further, the rule is in excess of statutory authority. It is contrary to Section 1557 of the ACA, 42 U.S.C. 18116, which prohibits sex discrimination in certain health programs and activities. Contrary to the statute, the regulation sanctions sex discrimination by allowing employers and universities to direct health insurance companies to prevent their employees and students from receiving contraceptive coverage. The rule is also contrary to Section 1554 of the ACA, which prohibits the Secretary of Health and Human Services from promulgating any regulation that “creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care.”⁵ As discussed throughout this comment, the proposed rule introduces multiple, complicated, and confusing barriers to care for women whose employers cite religion to object to cover women’s health services.

III. Contraception Is Critical to Women’s Health and Improves Women’s Economic and Social Status

Women face a unique set of healthcare challenges because they use more health services than men yet earn less on average than men.⁶ As a result, women face a high level of

⁵ 42 U.S.C. § 18114(1).

⁶ In 2013, per capita health care spending for women remained higher than spending for men. HEALTH CARE COST INST., 2013 HEALTH CARE COST AND UTILIZATION REPORT, 1 (Oct. 2014), available at: <http://www.healthcostinstitute.org/wp-content/uploads/2014/10/2013-HCCUR-12-17-14.pdf>; U.S. CENSUS BUREAU. INCOME AND POVERTY IN THE UNITED STATES: CURRENT POPULATION REPORTS 2016, TABLE 1. 2017..

health care insecurity which leads many women to forgo necessary care because of prohibitive patient cost-sharing. Before the ACA, one in seven women with private health insurance and nearly one-third of women covered by Medicaid either postponed or went without needed services in the prior year because they could not afford it.⁷ Women were spending between 30% and 44% of their total out-of-pocket health costs just on birth control.⁸ Because of the birth control benefit, women saved more than \$1.4 billion in out-of-pocket costs on birth control pills in 2013 alone.⁹

The goal of preventive health care is to help people control, track, and better manage their life-long health, and the health of their families. Access to contraception is a vital part in ensuring that individuals and families can make their own best decisions. Contraception and family planning are some of the most well-researched and proven effective methods of preventive care.¹⁰ They are particularly important in achieving Healthy People 2020's goal to "improve pregnancy planning and spacing, and prevent unintended pregnancy."¹¹ Women with unplanned pregnancies are more likely to delay prenatal care, leaving their health complications unaddressed and increasing risk of infant mortality, low birth weight, and preterm birth.¹² Women with unintended pregnancies are also at higher risk for maternal morbidity and mortality, maternal depression, or experiencing physical violence during pregnancy.¹³ Unintended pregnancy rates are higher in the United States than in most other developed countries, with approximately 45% of pregnancies unintended.¹⁴ Contraception is considered a major factor in reducing rates of maternal mortality and morbidity. Barriers to post-partum contraception are strongly associated with poor health outcomes including very low birth weight, infant mortality, and maternal mortality when women cannot ensure safe intervals between pregnancies.¹⁵

Access to contraception and preventive care is vital to ending health disparities that women of color face, including high rates of cervical cancer incidence and mortality, and unintended pregnancy. Women of color, women between the ages of 18 and 24, and low-income women continue to face high rates of unintended pregnancy, underscoring the

⁷ KAISER FAMILY FOUND. WOMEN'S HEALTH CARE CHARTBOOK. 2011.

⁸ *Id.*

⁹ Nora V. Becker and Daniel Polsky, *Women Saw Large Decrease In Out-Of-Pocket Spending For Contraceptives After ACA Mandate Removed Cost Sharing*, 34 HEALTH AFF., 1204-1211 (2015), available at <http://content.healthaffairs.org/content/34/7/1204.full.pdf+html>.

¹⁰ See IOM, *Clinical Preventive Services for Women: Closing the Gaps*, *supra* note 3.

¹¹ *Healthy People 2020: Family Planning*, OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION, <https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning> (last visited Dec. 3, 2017).

¹² Agustín Conde-Agudelo MD, MPH, et al. *Birth Spacing and Risk of Adverse Perinatal Outcomes: A Meta-Analysis*. 295 J. AM. MED. ASS'N 1809-23 (2006).

¹³ AO Tsui et al. *Family Planning and the Burden of Unintended Pregnancies*. 32 EPIDEMIOLOGIC REVIEWS 152-74 (2010).

¹⁴ Lawrence B. Finer and Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374 N. ENG. J. MED. 843-852 (2016).

¹⁵ Agustín Conde-Agudelo et al., *Effects of Birth Spacing on Maternal, Perinatal, Infant, and Child Health: A Systematic Review of Causal Mechanisms*, 43 STUD. FAM. PLAN. 93 (2012), https://www.k4health.org/sites/default/files/conde-agudelo_2012.pdf.

need for seamless access to contraception.¹⁶ While birth rates for females aged 15-19 have declined eight percent overall, disparities persist for communities of color. In 2015, Latina teens (females ages 15 to 19) experienced birth at more than twice the rate of their non-Hispanic, white peers. For the same year, Alaska Native/American Indian teens experienced birth at more than one and a half times the rate of their non-Hispanic, white peers.¹⁷ Unintended pregnancy is also a concern for those who face additional barriers to accessing health care services including economic instability and/or discrimination based on race, ethnicity, gender identity, or sexual orientation. Some studies show that, lesbian, gay, and bisexual youth are more likely to experience adolescent pregnancies than do youth who do not identify as a sexual minority.¹⁸

The medical and health-related standards of care for some women with chronic medical conditions or taking certain medications is to use contraception to prevent pregnancy until their conditions are under control to improve maternal health and birth outcomes. Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services violates medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.¹⁹ Recommendations for women with diabetes of childbearing potential include the following: the incorporation of preconception counseling into routine diabetes care for all adolescents of childbearing potential, discussion of family planning, and the prescription and use of effective contraception by a woman until she is ready to become pregnant.²⁰

There is also evidence that contraception provides health benefits for other medical conditions, including decreased bleeding and pain with menstrual periods and reduced risk of gynecologic disorders, including endometriosis, myoma, pelvic inflammatory disease, and a decreased risk of endometrial and ovarian cancer.²¹ Non-contraceptive health

¹⁶ GUTTMACHER INST., UNINTENDED PREGNANCY IN THE UNITED STATES, (Sept. 2016), <https://www.guttmacher.org/fact-sheet/unintended-pregnancy-united-states#8>.

¹⁷ *Social Determinants and Eliminating Disparities in Teen Pregnancy*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/teenpregnancy/about/social-determinants-disparities-teen-pregnancy.htm> (last updated Oct. 26, 2017).

¹⁸ Lisa L. Lindley, Katrina M. Walsemann, *Sexual Orientation and Risk of Pregnancy Among New York City High-School Students*, 105 AM. J. OF PUBLIC HEALTH 1379–86 (July 1, 2015); Karen Schantz, *Pregnancy Risk Among Bisexual, Lesbian, and Gay Youth: What Does Research Tell Us*, ACT FOR YOUTH CENTER OF EXCELLENCE (Apr. 2015), http://www.actforyouth.net/resources/rf/rf_lgb-prg_0415.pdf.

¹⁹ AM. DIABETES ASS'N, STANDARDS OF MEDICAL CARE IN DIABETES-2017, 40 DIABETES CARE S115, S117 (2017), available at:

http://care.diabetesjournals.org/content/diacare/suppl/2016/12/15/40.Supplement_1.DC1/DC_40_S1_final.pdf

²⁰ *Id.* at S114.

²¹ AE Schindler, *Non-Contraceptive Benefits of Oral Hormonal Contraceptives*, 11 Int. J. Endocrinol. Metab. 41-7 (2013); AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, ACCESS TO CONTRACEPTION. COMMITTEE OPINION No. 615, 125 Obstet Gynecol 250-5 (2015), available at:

benefits also include treatment for non-gynecologic conditions, such as acne.²²

By improving women's social and economic status, access to contraception promotes equal opportunities far beyond the health care realm. Contraception allows women to decide if and when to become parents, creating more professional and educational opportunities. Indeed, the U.S. Supreme Court found that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."²³ Increased control over reproductive decisions, in turn, provides women with educational and professional opportunities that have increased gender equality over the decades since birth control was introduced. Congress understood that the Women's Health Amendment would be "a huge step forward for justice and equality in our country."²⁴

Studies show that access to contraception has increased women's wages and lifetime earnings.²⁵ In fact, the availability of the oral contraceptive pill alone is associated with roughly one-third of the total wage gains for women born from the mid-1940s to early 1950s.²⁶ Access to oral contraceptives may also account for up to one-third of the increase in college enrollment by women in the 1970s, which was followed by large increases in women's presence in law, medicine, and other professions.²⁷ The Departments have previously acknowledged these significant benefits, noting that prior to the ACA's passage, disparities in healthcare coverage "place[d] women in the workforce at a disadvantage compared to their male co-workers," and that the contraceptive coverage benefit "furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force."²⁸ The significant impact that access to birth control has on women's educational and employment opportunities – and the significant

<https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/Access-to-Contraception>.

²² Schindler *supra* note 21.

²³ *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 856 (1992); see also *Erickson v. Bartell Drug Co.*, 141 F. Supp. 2d 1266, 1273 (W.D. Wash. 2001) ("[T]he adverse economic and social consequences of unintended pregnancies fall most harshly on women and interfere with their choice to participate fully and equally in the marketplace and the world of ideas.") (internal quotations omitted).

²⁴ 155 Cong. Rec. S12,033, S12,052 (daily ed. Dec. 1, 2009) (statement of Sen. Franken).

²⁵ See, e.g., Jennifer J. Frost & Laura Duberstein Lindberg, Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics, 87 *CONTRACEPTION* 465, 467 (2013); Adam Sonfield, et al., Guttmacher Inst., The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children (2013), available at <http://www.guttmacher.org/pubs/social-economic-benefits.pdf>.

²⁶ See Martha J. Bailey et al., *The Opt-in Revolution? Contraception and the Gender Gap in Wages*, 19, 26 (NAT'L BUREAU OF ECON. RESEARCH, Working Paper no. 17922, 2012), <http://www.nber.org/papers/w17922.pdf> (last visited Dec. 3, 2017).

²⁷ Heinrich H. Hock, *The Pill and the College Attainment of American Women and Men*, Fla. State Univ., 19, 2007; Claudia Goldin & Lawrence F. Katz, *The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions*, 110 *J. of Pol. Econ.* 730, 749 (2002), <https://dash.harvard.edu/handle/1/2624453>.

²⁸ Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 *Fed. Reg.* 8,725, 8,728 (Feb. 15, 2012).

impact on women’s health that educational and employment achievement have as well – makes access to contraceptive coverage even more critical.

IV. The IFR Imposes Financial and Nonfinancial Obstacles to Women Accessing Their Choice of Contraception

The exemptions put in place by the IFR erect significant barriers for employees and their dependents to obtain contraceptives (e.g., identify and enroll in another health plan or health insurance program, receive contraceptive care from one provider and other primary and preventive care from a different provider, pay up-front costs, and hope to receive reimbursement later). The Departments dismiss the impact that these burdens would have on women. However, studies assessing the attitudes and behaviors associated with unintended pregnancy have found that women engaging in unprotected sex frequently report barriers—financial *and* nonfinancial—in accessing birth control.²⁹ For this reason, research recommends that policies not only make contraceptive methods affordable, but also “simple to . . . obtain.”³⁰ The contraceptive coverage requirement is in accord with this research, and seeks to make contraception affordable and easy to access to enable women to decide when and whether to become pregnant. In contrast to the research, the IFR makes contraception unaffordable and inaccessible to many women, and creates major obstacles to avoiding unwanted pregnancy.

a. In Allowing Cost-Sharing, the IFR Will Reduce Use of Preventive Services

Cost is a significant barrier to utilization of preventive services.³¹ Prior to enactment of the ACA, individuals used preventive services at about half the rate recommended by medical standards of care.³² Low-income individuals and people of color used fewer preventive care

²⁹ See, e.g., Geraldine Oliva et al., *What High Risk Women are Telling Us about Access to Primary and Reproductive Health Care and HIV Prevention Services*, 11 AIDS PREVENTION PREVIEW 513, 515-21 (1999) (identifying barriers to care as including cost of health care, perceived poor quality of care and experiences of discrimination and stigmatization, geographic accessibility, fear of legal/social services punitive actions, misperceptions about the efficacy of birth control methods and condom usage); Adejoke Ayoola et al., *Reasons for Unprotected Intercourse in Adult Women*, 41 J. OF WOMEN'S HEALTH 271, 304-09 (2007) (discussing multiple reasons women have unprotected sex).

³⁰ Diana Greene Foster et al., *Attitudes Toward Unprotected Intercourse and Risk of Pregnancy Among Women Seeking Abortion*, 22 WOMEN'S HEALTH ISSUES e149, e154 (2011).

³¹ See, e.g., Geetesh Solanki et al., *The Direct and Indirect Effects of Cost-Sharing on the Use of Preventive Services*, 34 HEALTH SERVS. RESEARCH 1331, 1347-48 (2000); Dahlia K. Remler & Jessica Greene, *Cost-Sharing: A Blunt Instrument*, 30 ANNUAL REV. PUB. HEALTH 293, 296 (2009) (“Even modest cost-sharing may dissuade people from preventive care that might provide great value in the future.”); Andrew J. Karter, et al., *Out-of-Pocket Costs and Diabetes Preventive Services: The Translating Research Into Action for Diabetes (TRIAD) Study*, 26 DIABETES CARE 2294, 2296 (2003) (recommending plans and employers evaluate impact of cost-sharing on use of preventive care); KATHLEEN N. LOHR ET AL., RAND CORP., USE OF MEDICAL CARE IN THE RAND HEALTH INSURANCE EXPERIMENT: DIAGNOSIS- AND SERVICE-SPECIFIC ANALYSES IN A RANDOMIZED CONTROLLED TRIAL 30 (1986), <https://www.rand.org/content/dam/rand/pubs/reports/2006/R3469.pdf> (finding that cost-sharing is more likely to reduce visits for preventive care than chronic care).

³² P'SHIP FOR PREVENTION, PREVENTIVE CARE: A NATIONAL PROFILE ON USE, DISPARITIES, AND HEALTH BENEFITS 8 (2007), <http://www.rwjf.org/content/dam/farm/reports/reports/2007/rwjf13325> (“Among the 12 preventive services examined in this report, 7 are being used by about half or less of the people who should be using

services than non-Hispanic whites.³³ Compared to men, women were “more likely to forgo needed care because of cost and to have problems paying their medical bills, accrue medical debt, or both.”³⁴ The Departments claim that women who are unable to obtain no-cost coverage through their employer-sponsored health plans have other avenues for obtaining preventive services, particularly government sponsored programs for low-income people.³⁵ However, cost barriers to obtaining preventive services are prevalent not just for individuals that would meet eligibility requirements for such programs. The “[d]ifferences between men and women who reported problems accessing needed care persisted across all income groups, but were widest among adults with moderate incomes,” according to a 2009 study.³⁶ That study found that sixty-five percent of women with incomes between \$20,000 and \$39,999 experienced problems accessing health care services because of cost.³⁷

Individuals pay for their health insurance through premiums and cost-sharing.³⁸ Cost-sharing is the portion of health care expenses not covered by the insurer that the insured must pay out-of-pocket.³⁹ Cost-sharing includes deductibles, which are the amounts a person must pay out-of-pocket before the insurer will cover any expenses during a given benefit period, as well as copayments and coinsurance that insureds must pay out-of-pocket when they use a service or purchase a product (e.g., for a doctor visit or prescription drug).⁴⁰ The imposition of cost-sharing at the point of service is generally justified as a means of discouraging the use of non-essential services and reducing costs, though its efficacy at achieving these goals is not established.⁴¹

A large body of literature concludes that cost-sharing reduces use of medically necessary, valuable services, as opposed to merely discouraging overuse of unnecessary services.⁴²

them. Racial and ethnic minorities are getting even less preventive care than the general U.S. population.”); see also Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635, 2641 (2003) (discussing a 2003 study of adults living in 12 metropolitan areas in United States and finding “46.5% of participants did not use recommended care”).

³³ Lawrence O. Gostin, *Securing Health or Just Health Care? The Effect of the Health Care System on the Health of America*, 39 ST. LOUIS U. L. J. 7, 32 (1994); P’SHP FOR PREVENTION, *supra* note 14, at 7.

³⁴ SHEILA D. RUSTGI ET AL., THE COMMONWEALTH FUND, WOMEN AT RISK: WHY MANY WOMEN ARE FORGOING NEEDED HEALTH CARE 1-2 (2009), http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf.

³⁵ 82 Fed. Reg. 47,803.

³⁶ RUSTGI ET AL., *supra* note 34 at 4.

³⁷ *Id.*

³⁸ David Machledt & Jane Perkins, *Medicaid Premiums & Cost-Sharing* 1 (2014), <http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing#.WgCFehNSzeQ>.

³⁹ Dahlia K. Remler & Jessica Greene, *Cost-Sharing: A Blunt Instrument*, 30 ANNUAL REV. PUB. HEALTH 293, 294 (2009).

⁴⁰ *Id.*

⁴¹ Emmett B. Keeler, RAND Corp., *Effects of Cost Sharing on Use of Medical Services and Health*, 8 MED. PRAC. MGMT 317, 318-19 (1992), <https://www.rand.org/pubs/reprints/RP1114.readonline.html>.

⁴² See generally Katherine Swartz, Robert Wood Johnson Found., *Cost-Sharing: Effects on Spending and Outcomes* (2010), http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2010/rwjf402103/

According to the Institute of Medicine (“IOM”), a division of the National Academies of Sciences, Engineering, and Medicine, “[s]tudies have . . . shown that even moderate copayments for preventive services . . . deter patients from receiving those services.”⁴³ The RAND Health Insurance Experiment (“HIE”), conducted from 1971 to 1986, remains the longest-term randomized experiment studying the impact of cost-sharing on medical service utilization and health outcomes.⁴⁴ The HIE found that although higher cost-sharing reduced overall use of services and total health care expenditures, it also reduced use of essential health care services and produced some negative health outcomes.⁴⁵ The reductions in utilization found by the HIE were more prevalent in the context of preventive care than chronic care and particularly prevalent in the rate of care sought by low-income people.⁴⁶

A 2001 to 2004 study of 366,745 patients enrolled in 174 Medicare managed care plans found that the imposition of cost-sharing reduced mammography screening.⁴⁷ The study concluded that “[f]or cost-effective preventive services such as mammography, exempting elderly beneficiaries from cost-sharing may increase rates of appropriate use.”⁴⁸ Another study of 11,000 employees with employer-sponsored coverage found that cost-sharing reduced use of pap smears, preventive counseling, and mammography.⁴⁹ Because the IFR allows employers to eliminate cost-sharing protections for their employees, it will have the effect of decreasing preventive care utilization.

b. By Imposing Cost Barriers, the IFR Will Prevent Women from Accessing Contraception, Particularly the Most Effective Methods of Contraception

High out-of-pocket costs are one of the major barriers to consistent contraceptive use by women.⁵⁰ It is not surprising, then, that lower-income women are the least likely to have the

subassets/rwjf402103_1; Solanki et al., *supra* note 31, at 1347-48; Robert H. Brook et al., RAND Corp., *The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate* 3 (2006), http://www.rand.org/pubs/research_briefs/RB9174.html. For example, studies have shown increased adherence to key preventive medications, such as hypertensives, when cost-sharing was reduced or eliminated. See Niteesh K. Choudhry et al., *Full Coverage for Preventive Medications after Myocardial Infarction*, 365 NEW ENG. J. MED. 2088, 2091-96 (2011); Niteesh K. Choudhry et al., *At Pitney Bowes, Value-Based Insurance Design Cut Copayments and Increased Drug Adherence*, 29 HEALTH AFF. 1995, 1995 (2010). Such medications are among the most cost effective treatments available, and better adherence has been consistently associated with improved health outcomes. Michael T. Eaddy et al., *How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review*, 37 PHARMACY & THERAPEUTICS 45, 47 (2012).

⁴³ IOM, *Clinical Preventive Services for Women: Closing the Gaps*, *supra* note 3, at 19.

⁴⁴ Keeler, *supra* note 41, at 320.

⁴⁵ *Id.* at 318-19; Brook et al., *supra* note 42, at 2.

⁴⁶ Kathleen N. Lohr et al., *supra* note 31, at 29.

⁴⁷ Amal N. Trivedi et al., *Effect of Cost-sharing on Screening Mammography in Medicare Health Plans*, 358 NEW ENG. J. MED. 375, 381-82 (Jan. 24, 2008).

⁴⁸ *Id.*

⁴⁹ Solanki et al., *supra* note 31, 1342-43; see also Machledt & Perkins, *supra* note 38, at 2-3.

⁵⁰ Su-Ying Liang et al., *Women’s Out-of-Pocket Expenditures and Dispensing Patterns for Oral Contraceptive Pills between 1996 and 2006*, 83 CONTRACEPTION 491, 531 (2010); see also IOM, *Clinical Preventive Services for Women: Closing the Gaps*, *supra* note 3, at 109.

resources to obtain reliable methods of family planning and are the most likely to be impacted negatively by unintended pregnancy.⁵¹

A 2010 study found that privately insured women with prescription drug coverage paid out-of-pocket on average \$14 per oral contraceptive pill pack or approximately half of the cost of the pills.⁵² Studies consistently find that “[e]ven small increments in cost-sharing have been shown to reduce the use of preventive services.”⁵³ The IOM has accordingly recognized that the “elimination of cost-sharing for contraception therefore could greatly increase its use, including use of the more effective and longer-acting methods.”⁵⁴

In this regard, the California Kaiser Foundation Health Plan’s experience is informative. In 2002, the California Kaiser Foundation Health Plan eliminated copayments for the most effective contraceptive methods (intrauterine devices, injectables, and implants).⁵⁵ Prior to the change, users paid up to \$300 for a five-year contraceptive method; after elimination of the copayment, use of these methods increased by 137%.⁵⁶

Similarly, the Contraceptive CHOICE Project—a large prospective cohort study of nearly 10,000 adolescents and women in the St. Louis, Missouri area—provided participants a choice of no-cost contraception and followed them for two to three years.⁵⁷ The study concluded that providing no-cost contraception significantly allowed young women to avoid unintended pregnancy.⁵⁸ The study participant teen birth rate was 6.3 per 1,000 teens compared to the national average of 34.1 per 1,000 teens.⁵⁹ The researchers concluded that providing access to no-cost contraception greatly increased the ability of adolescents and women in the St. Louis region to select the most effective methods of contraception, thereby allowing them to reduce unintended pregnancies and abortions.⁶⁰ Based on their findings, the researchers estimated that providing no-cost contraception to all women would allow them to avoid unintended pregnancy.⁶¹ Because the IFR allows for contraceptive cost-sharing, it will reduce contraceptive use, particularly of the most effective methods.

⁵¹ See Rustgi et al., *supra* note 34, at 4-5 (explaining that women’s lower incomes and higher demands for health care, as compared to men, put them at increased risk for accruing medical debt and likelihood of putting off care); Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, 38 PERSP. ON SEXUAL & REPROD. HEALTH 90, 92-94 (2006) (finding that women with lower incomes have higher rates of unintended pregnancy as compared to women with higher incomes).

⁵² Liang et al., *supra* note 50, at 530-31.

⁵³ See IOM, *Clinical Preventive Services for Women: Closing the Gaps*, *supra* note 3, at 109.

⁵⁴ *Id.*

⁵⁵ Kelly Cleland et al., *Family Planning as Cost-Saving Preventive Health Service*, 364 NEW ENG. J. MED. e.37(1), e.37(2) (2011).

⁵⁶ *Id.*

⁵⁷ Jeffrey F. Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120(6) OBSTETRICS & GYNECOLOGY 1291, 1291-92 (2012).

⁵⁸ *Id.* at 1295-96.

⁵⁹ *Id.* The researchers “evaluated teenage birth . . . as a proxy for unintended pregnancy, as up to 80% of these births are unintended.” *Id.*

⁶⁰ *Id.* at 1295-96.

⁶¹ *Id.* at 1291-97.

c. *By Eliminating Cost Barriers, the Preventive Services Coverage Requirement in the ACA Has Been Successful in Improving Access to Contraception*

The ACA reflects the well-documented body of research that out-of-pocket costs for health care services are a problematic barrier to medication adherence.⁶² By removing cost barriers, the ACA is proving to be effective at achieving this compelling governmental interest in increasing access to contraception, and in impacting women's ability to decide when and if to become pregnant. In the Guttmacher Institute's Continuity and Change in Contraceptive Use study, researchers surveyed women aged eighteen to thirty-nine years about their contraceptive use before and after the contraceptive coverage requirement went into wide-scale effect.⁶³ The results show that the proportion of privately insured women with no out-of-pocket cost for their oral contraceptives increased from fifteen percent to sixty-seven percent; for injectable contraception, from twenty-seven percent to fifty-nine percent; for the vaginal ring, from twenty percent to seventy-four percent; and for the intrauterine device, from forty-five percent to sixty-two percent.⁶⁴ As rates of contraceptive coverage without cost-sharing increased, so did contraceptive access.⁶⁵ A report from the IMS Institute for Healthcare Informatics found that 24.4 million more prescriptions for oral contraceptives with no copayment were filled in 2013 than in 2012.⁶⁶ According to that report, oral contraceptives accounted for the largest increases in prescriptions dispensed without a copayment.⁶⁷ Reducing the cost barrier to contraception is resulting in greater access to contraception, just as the ACA intended.

V. The IFR Is Inconsistent with Evidence-Based Preventive Care

Insurance coverage policies must be based on research, evidence, and medical and health-related facts, and must be responsive to individual patient and consumer needs and wishes. Consumers require medically accurate, evidence-based, unbiased comprehensive health care services so that they can use their own decision making capacity to choose health care services that comport with their individual morality and circumstances. Because the IFR promotes deviation from these scientific standards, it is inconsistent with promoting

⁶² See, e.g., Michael E. Chernew et al., *Impact of Decreasing Copayments on Medication Adherence Within a Disease Management Environment*, 27 HEALTH AFF. 103, 111 (2008) (finding that "increased cost sharing leads to decreased adherence to potentially life-saving medications, with likely serious deleterious health effects"); Niteesh K. Choudhry et al., *Should Patients Receive Secondary Prevention Medications for Free After a Myocardial Infarction? An Economic Analysis*, 26 HEALTH AFF. 186, 186 (2007) (finding that cost-sharing can cause medication underuse).

⁶³ Adam Sonfield et al., *Impact of the Federal Contraceptive Coverage Guarantee on Out-of-Pocket Payments for Contraceptives: 2014 Update*, 91 CONTRACEPTION 44, 44-45 (2014). The federal government phased in the contraceptive coverage requirement starting in August 2012, and it went into wide-scale effect in January 2013. *Id.* at 44.

⁶⁴ *Id.* at 45-47.

⁶⁵ See IMS Inst. for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* (2014).

⁶⁶ *Id.* at 16.

⁶⁷ *Id.* at 13.

preventive care and strengthening the economic and social well-being of individuals across the lifespan.

As the nation’s health policy center, HHS’ policies and activities must be firmly based on scientifically valid and appropriate terms and evidence. The IFR does not meet the high standard of scientific evidence used by the IOM and WPSI, instead prioritizing the religious beliefs of individuals over evidence-based medical recommendations. The Departments make several false and misleading statements in this Rule discussed below that undermine the contraceptive coverage benefit. In the face of these facts, the IFR goes so far as to imply that birth control is not health care at all.

a. Contraceptives Do Not Interfere with an Existing Pregnancy

Policies that restrict women’s access to preventive health care should not be based on falsehoods that are not supported by science. The Rule takes issue with the IOM recommended coverage of the full range of FDA-approved contraceptive methods because it includes “certain drugs and devices... that many persons and organizations believe are abortifacient—that is, as causing early abortion.”⁶⁸ Regardless of some personal beliefs, the evidence is clear. FDA-approved contraceptive methods are not abortifacients. Every FDA-approved contraceptive acts before implantation, does not interfere with a pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus.⁶⁹

b. Contraceptives Are Medication and Carry Risks Like Any Medication

The Rule raises concerns about the “negative health effects” of contraception.⁷⁰ As with any medication, certain types of contraception may be contraindicated for patients with certain medical conditions, including high blood pressure, lupus, or a history of breast cancer.⁷¹ Specifically, the Rule suggests an increased risk of venous thromboembolism (VTE). In fact, VTE among oral contraceptive users is very low and is much lower than the risk of VTE during pregnancy or in the immediate postpartum period.⁷² The Rule also

⁶⁸ 82 Fed. Reg. 47,794.

⁶⁹ Brief for Physicians for Reproductive Health et al. as Amici Curiae Supporting Petitioners, *Sebelius v. Hobby Lobby Stores, Inc.*, 573 U.S. __ 12-21 (2014) (No. 13-354), available at: <https://www.scribd.com/document/187287249/Brief-of-Amici-Curiae-Physicians-for-Reproductive-Health-et-al-in-Support-of-Petitioners>.

⁷⁰ 82 Fed. Reg. 47,804.

⁷¹ AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, PROGESTIN-ONLY HORMONAL BIRTH CONTROL: PILL AND INJECTION, FAQ No. 86 (2014); AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, COMBINED HORMONAL BIRTH CONTROL: PILL, PATCH, AND RING, FAQ No. 185 (2014).

⁷² AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS, RISK OF VENOUS THROMBOEMBOLISM AMONG USERS OF DROSPIRENONE-CONTAINING ORAL CONTRACEPTIVE PILLS, COMM. OPINION No. 540, 120 OBSTET GYNECOL 1239-42 (2012), available at <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Gynecologic-Practice/co540.pdf?dmc=1&ts=20161007T0314567246>.

suggests contraception increases the risk of breast cancer, but there is no proven increased risk of breast cancer among contraceptive users, particularly those under 40.⁷³

c. Contraceptives Make Sex Among Adolescents Healthier, Not More Likely to Happen

The Rule suggests the contraceptive coverage benefit could “affect risky sexual behavior in a negative way.”⁷⁴ Increased access to contraception is not associated with increased unsafe sexual behavior or increased sexual activity.⁷⁵ In fact, research has shown school-based health centers that provide access to contraceptives are proven to increase use of contraceptives by already sexually active students, not to increase onset of sexual activity.⁷⁶ Overall, increased access to and use of contraception has contributed to a dramatic decline in rates of adolescent pregnancy.⁷⁷ More females are using contraception the first time they have sex.⁷⁸

The Departments should rescind the IFR because it is not evidence-based and does not withstand basic scientific scrutiny.

VI. The IFR Undermines Congress’ Express Intent that Contraception Be Covered As a Preventive Service

The Departments ignore Congress’s express intent that contraception be covered as a preventive service under the ACA.

a. Congress Intended the ACA to Require Contraceptive Coverage

When Congress passed the Women’s Health Amendment, it meant “to ensure that recommended preventive services for women are covered adequately by non-grandfathered group health plans and group health insurance coverage, recogniz[ing] that women have unique health care needs and burdens.”⁷⁹ Allowing more entities to deprive

⁷³ KATHRYN M. CURTIS ET AL., 65 MORBIDITY & MORTALITY WKLY REP. 1-66, U.S. SELECTED PRACTICE RECOMMENDATIONS FOR CONTRACEPTIVE USE, (2016), available at <https://www.cdc.gov/mmwr/volumes/65/rr/rr6504a1.htm>.

⁷⁴ 82 Fed. Reg. 47,805.

⁷⁵ Sheila Desai et al., *Understanding the Decline in Adolescent Fertility in the United States*, 59 J. ADOLESCENT HEALTH, 2007-2012, 577, 577 (2016) available at: [http://www.jahonline.org/article/S1054-139X\(16\)30172-0/fulltext](http://www.jahonline.org/article/S1054-139X(16)30172-0/fulltext); JL Meyer et al., *Advance Provision of Emergency Contraception Among Adolescent and Young Adult Women: A Systematic Review of Literature*. 24 J. PEDIATR ADOLESC GYNECOL. 2-9 (2011).

⁷⁶ M Minguet et al., *Reproductive Health Impact of a School Health Center*, 56 J. ADOLESCENT HEALTH, 338-44 (2015); JA Knopf et al., *Community Preventive Services Task Force. School-Based Health Centers to Advance Health Equity: A Community Guide Systematic Review*. 51 AM. J. PREVENTIVE MED. 114-26 (2016).

⁷⁷ See Desai *supra* note 75, at 577-83.

⁷⁸ *Id.*

⁷⁹ Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,727 (Feb. 15, 2012).

women of contraceptive coverage, as the IFR does, strikes at the very purpose of the contraceptive coverage requirement.

Indeed, in enacting the Women’s Health Amendment, Congress recognized that the failure to cover women’s preventive health services meant that women paid more in out-of-pocket costs than men for necessary preventive care and in some instances were unable to obtain this care at all because of cost barriers:

“Women must shoulder the worst of the health care crisis, including *outrageous discriminatory practices in care and coverage*. . . . In America today, too many women are delaying or skipping preventive care because of the costs of copays and limited access. In fact, more than half of women delay or avoid preventive care because of its cost. *This fundamental inequity in the current system is dangerous and discriminatory and we must act.*⁸⁰ [emphasis added]

In considering the Amendment, Congress expressed its expectation that the preventive services covered would include family planning services. For example, Senator Gillibrand stated, “With Senator Mikulski’s amendment, even more preventive screening will be covered, including for . . . family planning.”⁸¹ Senator Franken also said in regards to the Women’s Health Amendment, “[A]ffordable family planning services must be accessible to all women in our reformed health care system.”⁸² Congress did not add any exemption to the women’s preventive services provision.

b. The Departments Cannot Point to Other “Exemptions” to Justify the Rule

The Departments look to the mere existence of exemptions in *other* statutes as well as the ACA’s “grandfathering” provision to justify the sweeping exemptions in the IFR. Neither justify the exemptions.

The Departments attempt to construct a foundation for the IFR’s exemptions by reference to existing federal laws that allow health care entities to refuse to treat a woman seeking an abortion, and other laws that allow religious refusals to provide certain health care services. Not only are these laws irrelevant to the women’s preventive services provision of the ACA, but the Departments’ attempt to misconstrue these existing laws to create a justification

⁸⁰ 155 CONG. REC. S12,021, S12,027 (daily ed. Dec. 1, 2009) (statement of Sen. Gillibrand); *See also Id.* at S12,026 (daily ed. Dec. 1, 2009) (statement of Sen. Mikulski) (noting that the Women’s Health Amendment was a response to “punitive practices of insurance companies that charge women more and give [them] less in a benefit.”).

⁸¹ 155 CONG. REC. S12,021, S12,027 (daily ed. Dec. 1, 2009).

⁸² 155 CONG. REC. S12,033, S12,052 (daily ed. Dec. 1, 2009); *See also*, 155 CONG. REC. S12,106, S12,114 (daily ed. Dec. 2, 2009) (statement of Sen. Feinstein) (“[The Amendment] will require insurance plans to cover at no cost basic preventive services and screenings for women. This may include . . . family planning . . .”).

only further proves that there is no direct and clear authority for the Departments to create this exemption.

The Departments also point to “grandfathered” plans as further justification for its action. But, the existence of plans that are grandfathered from the ACA’s contraceptive coverage requirement does not diminish Congress’s intent in maximizing the number of women who have contraceptive coverage.⁸³ Grandfathered plans were always expected to be phased out over time, and research shows the number of employees enrolled in such plans have indeed decreased steadily since 2010.⁸⁴ Grandfathered plans are intended as a temporary means for transitioning employers to full-compliance plans.⁸⁵ The Administration acknowledges that grandfathered plans will likely cease to exist within a few years of the ACA’s enactment, stating that grandfathering “minimiz[es] market disruption and put[s] us on a glide path toward the competitive, patient-centered market of the future.”⁸⁶ As a result of the ACA’s grandfathering provision, the grandfathering regulations, other ACA constraints, and market incentives, grandfathered plans are nearly impossible to abide with in the near and long term, and are continuously moving toward total disappearance.⁸⁷ Indeed the number of employer-sponsored grandfathered plans has decreased steadily since the ACA’s enactment.⁸⁸ In 2017, 17% of covered workers are enrolled in a grandfathered plan, continuing a decline from 23% in 2016, 26% in 2014, 36% in 2013, and 48% in 2012.⁸⁹ Additionally, federal statutes “often include exemptions for small employers,

⁸³ See *Priests for Life, v. U.S. Dep’t of Health & Human Servs.*, 772 F.3d 229, 266 (D.C. Cir. 2014) (“The government’s interest in a comprehensive, broadly available system is not undercut by . . . the exemptions for religious employers, small employers and grandfathered plans. The government can have an interest in the uniform application of a law, even if that law allows some exceptions.”).

⁸⁴ GARY CLAXTON ET AL., KAISER FAMILY FOUNDATION, EMPLOYER HEALTH BENEFITS 2017 ANNUAL SURVEY 204 (2017), <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>. See also Sara R. Collins, *Grandfathered vs. Non-Grandfathered Health Plans Under the Affordable Care Act: Striking the Right Balance*, THE COMMONWEALTH FUND (June 22, 2010),

<http://www.commonwealthfund.org/publications/blog/grandfathered-vs-non-grandfathered-plans>; Larry Levitt et al., *Assessing ACA Marketplace Enrollment*, KAISER FAMILY FOUNDATION (Mar. 4, 2016),

<https://www.kff.org/health-reform/issue-brief/assessing-aca-marketplace-enrollment/>; *Grandfathering Explained*, KAISER FAMILY FOUNDATION (Sep. 8, 2011), <https://www.kff.org/health-reform/perspective/grandfathering-explained/>; Sarah Barr, *FAQ: Grandfathered Health Plans*, KAISER HEALTH NEWS (Nov. 13, 2013), <https://khn.org/news/grandfathered-plans-faq/>; Elizabeth Weeks Leonard, *Can You Really Keep Your Health Care Plan? The Limits of Grandfathering under the Affordable Care Act*, 36 J. CORP. L. 753 (2011), http://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1684&context=fac_artchop.

⁸⁵ Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,887 n.49 (July 2, 2013), <https://www.federalregister.gov/documents/2013/07/02/2013-15866/coverage-of-certain-preventive-services-under-the-affordable-care-act>; *Hobby Lobby v. Burwell*, 134 S. Ct. 2751, 2800-01 (2014) (Ginsburg, J., dissenting). See also *Grandfathering Explained*, *supra* note 84; Collins, *supra* note 84; Levitt, *supra* note 84; Barr, *supra* note 84; Leonard, *supra* note 84.

⁸⁶ *Keeping the Health Plan You Have: The Affordable Care Act and “Grandfathered” Health Plans*, THE CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT (June 14, 2010), <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/keeping-the-health-plan-you-have-grandfathered.html>. See also Leonard, *supra* note 84.

⁸⁷ Leonard, *supra* note 84.

⁸⁸ CLAXTON ET AL., *supra* note 84.

⁸⁹ *Id.*

and such provisions have never been held to undermine the interests served by these statutes.”⁹⁰

VII. The IFR Violates Other Statutory and Constitutional Protections for Women

By creating broad exemptions to the ACA’s birth control benefit, the IFR singles out health insurance that is essential for women’s health and equality.

Religious arguments have long been used to thwart women’s equality, just as they have been used to thwart racial equality.⁹¹ But those efforts have been rejected repeatedly. For example, in passing Title VII of the Civil Rights Act of 1964, Congress barred workplace discrimination based on a variety of factors including race and sex, over objections based on religion.⁹² And as society has evolved beyond a religiously imbued vision of women as mothers and wives, courts have rejected efforts to allow religious exemptions to undermine civil rights protections for women.⁹³

Like Title VII and other civil rights laws, the birth control benefit was intended to address longstanding discrimination and ensure women equal access to the preventive services that allow them to be full participants in society. In interfering with that access, the IFR targets women for adverse treatment, resulting in health insurance that covers preventive care that men need but not care that women need. It interferes with the right to contraception encompassed by the fundamental constitutional right to liberty. As a result, the IFR discriminates against women on the basis of sex, in violation of the Due Process Clause of the Fifth Amendment, which guarantees people equal protection of the laws. The IFR also violates Section 1557 of the ACA, which prohibits discrimination on the basis of sex in “any health program or activity, any part of which is receiving Federal financial assistance . . . or under any program or activity that is administered by an Executive Agency.”⁹⁴

VIII. The Departments’ Explanation that Other Programs Can Meet the Need for Birth Control Coverage Is Faulty

⁹⁰ *Hobby Lobby*, 134 S. Ct. at 2800 (Ginsburg, J., dissenting); see, e.g., Family and Medical Leave Act of 1993, 29 U.S.C. § 2611(4)(A)(i) (applicable to employers with 50 or more employees); Age Discrimination in Employment Act of 1967, 29 U.S.C. § 630(b) (originally exempting employers with fewer than 50 employees, Age Discrimination in Employment Act of 1967, Pub. L. No. 90-202, 81 Stat. 605 (1967), the statute now governs employers with 20 or more employees); Americans with Disabilities Act, 42 U.S.C. § 12111(5)(A) (applicable to employers with 15 or more employees); Title VII, 42 U.S.C. § 2000e(b) (originally exempting employers with fewer than 25 employees).

⁹¹ See, e.g., Brief for American Civil Liberties Union et al. as Amici Curiae Supporting Respondents, *Zubik v. Burwell*, 578 U.S. ___, 21 (2016) (Nos. 14-1418, 14-1453, 14-1505, 15-35, 15-105, 15-119, and 15-191), available at :

https://www.aclu.org/sites/default/files/field_document/02.17.16_amicus_brief_in_support_of_respondents-aclu_et_al.pdf.

⁹² *Id.* at 19.

⁹³ *Id.* at 24-27.

⁹⁴ 2 U.S.C. § 18116.

The Departments assert that existing government-sponsored programs, such as Medicaid and Title X, and state coverage requirements can serve as alternatives or safeguards for individuals who will lose access to contraceptive coverage without cost sharing as a result of this IFR.⁹⁵ This assertion fails to recognize that Medicaid and Title X are not designed to absorb the needs of higher income, privately insured individuals and do not have the capacity to meet the needs of current enrollees *and* those seeking care at Title X health centers. With respect to the state laws, the Departments' claim misconstrues the scope and protections of state contraceptive coverage laws, which cannot fill in the coverage gaps caused by this IFR.

a. Medicaid and Title X Programs Are Not Designed to Meet The Needs of Individuals Who Will Lose Contraceptive Coverage

Safety net programs like the Title X family planning program and Medicaid are not designed to absorb the unmet needs of higher-income, insured individuals. Enacted in 1970, Title X is the nation's only dedicated source of federal funding for family planning services.⁹⁶ While Title X-funded health centers provide care to all patients, federal law requires them to give priority to "persons from low-income families."⁹⁷ Low-income individuals receive services at low or no cost depending on their family income.⁹⁸ Congress did not design Title X as a substitute for employer-sponsored coverage. The Title X statute and regulations contemplate how Title X and third-party payers will work together to pay for care, directing Title X-funded agencies to seek payment from such third-party payers.⁹⁹

Medicaid is a source of coverage designed to meet the unique health care needs of individuals who are low-income. However, unlike Title X, which requires the health centers it funds to take all patients, Medicaid has income and other eligibility requirements for individuals to participate. Many individuals enrolled in Medicaid have extremely low incomes and minimal savings at hand. These individuals also face severe health problems and lack any resources to address these issues on their own, unlike individuals with higher incomes and employer-sponsored coverage. Moreover, while thirty-three states have expanded coverage under the Medicaid expansion option of the ACA, many individuals remain ineligible for this coverage.¹⁰⁰ In states that have not expanded Medicaid, income eligibility for this program is quite limited. The median income limit for parents in these states is an annual income of \$8,985 a year for a family of three in 2017, and in most states

⁹⁵ 82 Fed. Reg. 47803.

⁹⁶ See Fam. Plan. Servs. & Population Res. Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504.

⁹⁷ 42 CFR § 59.5 (a)(6-9).

⁹⁸ 42 U.S.C. § 300a-4(c)(2); 42 C.F.R. § 59.5(a)(7)-(8).

⁹⁹ 42 U.S.C. § 300a-4(c)(2) (prohibiting charging persons from a "low-income family" for family planning services "except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge"); 42 C.F.R § 59.5(a)(7), (9).

¹⁰⁰ KAISER FAMILY FOUND., STATUS OF STATE ACTION ON THE MEDICAID EXPANSION DECISION, <https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last updated Nov. 8, 2017).

that have not expanded Medicaid, childless adults remain ineligible for this program.¹⁰¹ Due to this, many low-income women who would be eligible to enroll in Medicaid under this option, depending on where they reside, are unable to do so. For many women who will lose access to the contraceptive coverage benefit, Title X and Medicaid will not be viable alternatives for securing contraceptive care and counseling.

b. Medicaid and Title X Programs Do Not Have Capacity to Meet The Increased Need for Contraceptive Care and Counseling That Will Result From the IFR

At a time when our nation's public health network is already burdened and under attack, it is critical to ensure that all women have access to contraceptive coverage and care. Medicaid is the nation's largest insurer, providing coverage to over 74 million people who are enrolled in the program, including many women of color.¹⁰² Medicaid enrollees have robust access to comprehensive health care, and Medicaid already operates as a very lean program. In spite of this, provider shortages have persisted. The majority (two-thirds) of state Medicaid programs face challenges to securing an adequate number of providers to furnish services to patients.¹⁰³ This is particularly true with respect to specialty providers, including OB/GYNs. A recent report from the HHS Office of Inspector General found that many Medicaid managed care plans had provider shortages, with only 42 percent of in-network OB/GYN providers able to offer appointments to new patients.¹⁰⁴

The IFR argues that Title X-funded health centers could fill the gap in contraceptive coverage by employer refusals, and would have to furnish care to more patients than are currently served by the program. However, the Title X provider network cannot meet the existing need for publicly funded family planning, let alone absorb the increase in demand that would result from the Department's rules. Since 2010, the reported annual number of clients served at Title X sites has dropped from approximately 5.2 million patients to just over 4 million.¹⁰⁵ This decline corresponds to over \$30 million in cuts to Title X's annual

¹⁰¹ RACHEL GARFIELD & ANTHONY DAMICO, KAISER FAMILY FOUND., THE COVERAGE GAP: UNINSURED POOR ADULTS IN STATES THAT DO NOT EXPAND MEDICAID, (2017), <https://www.kff.org/uninsured/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/>.

¹⁰² Thirty-one percent of Black women and twenty-seven percent of Latinas of reproductive age are enrolled in Medicaid. ADAM SONFIELD, GUTTMACHER INST., WHY PROTECTING MEDICAID MEANS PROTECTING SEXUAL AND REPRODUCTIVE HEALTH, 20 GUTTMACHER POL'Y REV. 39, 40 (2017), https://www.guttmacher.org/sites/default/files/article_files/gpr2003917.pdf. Nearly one-fifth (19 percent) of Asian American Pacific Islander women are enrolled in Medicaid, including women from Southeast Asian Communities. IN OUR OWN VOICE: NAT'L BLACK WOMEN'S REPROD. JUST. AGENDA ET AL., AMERICAN HEALTH CARE ACT THREATENS REPRODUCTIVE JUSTICE FOR WOMEN OF COLOR, 3 (2017), <http://www.nationalpartnership.org/research-library/repro/the-house-republican-repeal-bill-threatens-reproductive-justice-for-women-of-color.pdf>.

¹⁰³ U.S. GEN. ACCOUNTING OFFICE, STATES MADE MULTIPLE PROGRAM CHANGES, AND BENEFICIARIES GENERALLY ACCESS COMPARABLE TO PRIVATE INSURANCE, (Nov. 2012), available at: <http://www.gao.gov/assets/650/649788.pdf>; U.S. DEP'T OF HEALTH & HUMAN SERVS (HHS), OFFICE OF INSPECTOR GENERAL, ACCESS TO CARE: PROVIDER AVAILABILITY IN MEDICAID MANAGED CARE (Dec. 2014), <http://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf>.

¹⁰⁴ HHS, Access to Care: Provider Availability in Medicaid Managed Care, *supra* note 103 at 21.

¹⁰⁵ See C FOWLER ET AL., RTI INTERNATIONAL, FAMILY PLANNING ANNUAL REPORT: 2010 NATIONAL SUMMARY, (Sept. 2011), available at <https://www.hhs.gov/opa/sites/default/files/fpar-2010-national-summary.pdf>; CI FOWLER ET AL., RTI INTERNATIONAL, FAMILY PLANNING ANNUAL REPORT: 2016 NATIONAL SUMMARY, (Aug. 2017), available at <https://www.hhs.gov/opa/sites/default/files/title-x-fpar-2016-national.pdf>.

appropriated amount over the same period.¹⁰⁶ A recent study published in the American Journal of Public Health confirms that reductions in funding for Title X limit the number of patients Title X-funded providers are able to serve, concluding that Congress would have to increase federal funding for Title X by over \$450 million to adequately address the existing need for publicly funded contraception.¹⁰⁷ Requiring otherwise higher-income, privately insured individuals to use Title X-funded health centers would deplete resources from an already overburdened and underfunded program.

Moreover, legislative and administrative proposals, if implemented, would weaken the capacity of the Title X and Medicaid programs to serve current enrollees and patients. The House has proposed to defund the Title X program once again for FY 2018.¹⁰⁸ The President's FY 2018 budget plan proposed blocking low-income and uninsured patients from obtaining federally-funded health care services, including Title X-funded care, at Planned Parenthood health centers, even though Planned Parenthood health centers currently serve 41 percent of patients that access contraception through Title X nationwide.¹⁰⁹

Within the last year, as part of the numerous, failed attempts to repeal the ACA, policymakers have sought to radically alter the financial structure of Medicaid and continue to defund or interfere with patients' access to care under the Title X program.¹¹⁰ Policymakers continue to try to impose steep cuts to the Medicaid program through the budget process and to undermine the program through regulatory and administrative measures. HHS has made clear its intent to approve waivers of existing Medicaid rules and standards.¹¹¹ These waivers may very well include provisions that undermine the ability of

¹⁰⁶ *Funding History HHS.Gov* (2017), U.S. Dept. of Health and Human Servs., <https://www.hhs.gov/opa/title-x-family-planning/about-title-x-grants/funding-history/index.html> (last visited Nov 3, 2017).

¹⁰⁷ Euna M. August et al., *Projecting the Unmet Need and Costs for Contraception Services After the Affordable Care Act*, AM. J. PUB. HEALTH (2016), available at <http://doi.org/10.2105/AJPH.2015.302928>.

¹⁰⁸ *Title X, Budget & Appropriations*, Nat'l Family Planning & Reprod. Health Ass'n, <https://www.nationalfamilyplanning.org/title-x-budget-appropriations>, (last updated visited Nov. 3, 2017); Make America Secure and Prosperous Appropriations Act, 2018, H.R. 3354, 115th Cong. (2017) ("None of the funds appropriated in this Act may be used to carry out title X of the PHS Act.").

¹⁰⁹ KINSEY HASSTEDT, GUTTMACHER INST., BEYOND THE RHETORIC: THE REAL-WORLD IMPACT OF ATTACKS ON PLANNED PARENTHOOD AND TITLE X, GUTTMACHER POL'Y REV., (Aug. 2017), available at <https://www.guttmacher.org/gpr/2017/08/beyond-rhetoric-real-world-impact-attacks-planned-parenthood-and-title-x>; OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, THE PRESIDENT'S FISCAL YEAR 2018 BUDGET: OVERVIEW (May 2017), available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/budget/fy2018/fact_sheets/2018%20Budget%20act%20Sheet_Budget%20Overview.pdf (last visited Nov 3, 2017).

¹¹⁰ The most recent legislative proposal sponsored by Senators Lindsey Graham and Bill Cassidy would have decimated the Medicaid program by cutting over one trillion dollars to the program over the next ten years. CONG. BUDGET OFFICE, PRELIMINARY ANALYSIS OF LEGISLATION THAT WOULD REPLACE SUBSIDIES FOR HEALTH CARE WITH BLOCK GRANTS, 6, (Sept. 2017), <https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/53126-health.pdf>. The proposal would have repealed Medicaid expansion, converted Medicaid's financing structure to a per capita cap, and would have permitted states to block grant their Medicaid programs for certain communities, resulting in drastic cuts to coverage and services that individuals enrolled in Medicaid need and deserve. MARA YOUDELMAN & KIM LEWIS, NAT'L HEALTH LAW PROGRAM, TOP 10 CHANGES TO MEDICAID UNDER THE GRAHAM-CASSIDY BILL, (Sept. 14, 2017), <http://www.healthlaw.org/publications/browse-all-publications/top-10-changes-to-medicaid-under-graham-cassidy-bill#.Wft9mmhSzIV>.

¹¹¹ Letter from Secretary Tom E. Price and CMS Administrator, Seema Verma, to Governors (on file with NHeLP-DC), <https://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf>; Paige Winfield Cunningham, *States Will Be Allowed to Impose Medicaid Work Requirements, Top Federal Official Says*,

individuals qualified to enroll in Medicaid to receive the coverage and health care they need.

Regardless of the political proposals that would severely limit access to these programs, Medicaid and Title X are not designed to absorb the needs of higher income, privately insured individuals. These programs are not and cannot serve as alternatives for securing contraceptive care and counseling for individuals who will lose access because of this IFR.

c. State Contraceptive Parity Laws Are Insufficient to Fill in the Coverage Gaps Caused by This IFR

Similarly, the IFR suggests that the existence of state-level contraceptive coverage requirements somehow diminish the need for a federal requirement. This suggestion ignores the fact that many states do not have any contraceptive parity laws and that the federal contraceptive coverage requirement made several important advances over state laws in terms of cost-sharing protections.¹¹²

The major reason that state laws are insufficient is that they are preempted as applied to employers that provide self-insured health coverage; under the Employee Retirement Income Security Act of 1974, only Congress can regulate these plans, as the ACA does. These self-insured plans are estimated to cover 60% of covered workers nationwide, leaving state protections wholly irrelevant to women who access health care using these plans.¹¹³ Further, contraceptive parity laws, which are in effect in 24 states, require insurers to cover contraceptive services as they would any other medical or prescription drug service but do not eliminate copayments, deductibles and other out-of-pocket costs; 21 states and the District of Columbia have no coverage protections at all.¹¹⁴ Moreover, few state laws match the federal requirement in terms of the breadth and specificity of the contraceptive methods, services, and counseling that are included, making them inadequate to protect women from the harmful effects of losing contraceptive coverage as a result of the IFR.¹¹⁵

VI. Conclusion

WASH. POST (Nov. 7, 2017), https://www.washingtonpost.com/news/powerpost/wp/2017/11/07/states-will-be-allowed-to-impose-medicaid-work-requirements-top-federal-official-says/?utm_term=.0513a6c28c8e.

¹¹² Guttmacher Inst., INSURANCE COVERAGE OF CONTRACEPTIVES: STATE LAWS AND POLICIES, (2017), <http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives>.

¹¹³ See Claxton et al., *supra* note 84.

¹¹⁴ NAT'L WOMEN'S LAW CNTR., CONTRACEPTIVE EQUITY LAWS IN YOUR STATE: KNOW YOUR RIGHTS – USE YOUR RIGHTS, A CONSUMER GUIDE, (Aug. 27, 2012), <https://nwlc.org/resources/contraceptive-equity-laws-your-state-know-your-rights-use-your-rights-consumer-guide/>. Only four states, California, New York, Illinois, and Vermont, currently have laws in effect that are as extensive as the federal contraceptive coverage requirement.

¹¹⁵ For example, only three states currently require coverage of female sterilization, and only two states currently require coverage of methods sold over the counter (such as some types of emergency contraception). Several additional states have enacted new requirements that will take effect in 2018 or 2019. See Guttmacher Inst., INSURANCE COVERAGE OF CONTRACEPTIVES: STATE LAWS AND POLICIES, *supra* note 112.

Section 2713(a)(4) of the Public Health Service Act, and its implementing regulations, make access to contraception possible by ensuring that health plans in the individual and small group market adequately cover contraception without cost-sharing—cost-sharing that would otherwise reduce use of this necessary service. We strongly object to the Departments' efforts to undermine the ACA's contraceptive coverage requirement through this IFR and urge the Departments to strike the IFR in its entirety.

Thank you for your attention to our comments. If you have any questions or need any further information, please contact Susan Berke Fogel, Reproductive Health Director, at fogel@healthlaw.org.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth G. Taylor". The signature is written in a cursive, flowing style.

Elizabeth G. Taylor
Executive Director