December 4, 2017

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

Attention: CMS-9925-IFC

RE: Moral 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 Moral 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 in the Federal Register on 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'

[1] Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-10-13/pdf/2017-21852.pdf (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).

1444 I Street NW, Suite 1105 · Washington, DC 20005 · (202) 289-7661 · Fax (202) 289-7724
3701 Wilshire Boulevard, Suite 750 · Los Angeles, CA 90010 · (310) 204-6010 · Fax (213) 368-0774
200 N. Greensboro Street, Suite D-13 · Carrboro, NC 27510 · (919) 968-6308 · Fax (919) 968-8855
www.healthlaw.org

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, thus, 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 Department of Health and Human Services' ("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"), a division of the National Academies of Sciences, Engineering, and Medicine.[3] The ACA's requirements ensure that all women, regardless of where they work, have seamless access to all Food and Drug Administration ("FDA")-approved methods of contraception without cost-sharing.

The IFR exponentially increases the number of employers who are allowed to deny their employees contraceptive coverage. It exempts all non-profit employers, non-publicly traded for-profit employers, and institutions of higher education with a "moral" objection to contraception from complying with the contraceptive care requirement of the ACA. The IFR also gives exempted employers and institutions the authority to decide whether their employees and students receive independent contraceptive care coverage through the accommodation process.

We are very concerned that the IFR will deprive women of health care benefits that medical experts recognize as critical to ensuring reproductive health and well-being.[4] In broadly exempting nearly all employers from contraceptive coverage policies, the IFR gravely threatens women's access to their choice of contraceptive method and their ability to determine when and if to become pregnant. The exemption undermines the ACA's intention to ensure all women receive comprehensive contraceptive coverage of the full range of

---

[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)); Health Res. & Servs. Admin. (HRSA), *Women's Preventive Services: Required Health Plan Coverage Guidelines*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (HHS), 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), https://www.nap.edu/read/13181/chapter/1.

[4] *Committee Opinion: Increasing Access to Abortion*, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (2014), https://www.acog.org/-/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co613.pdf?dmc=1&ts=20171019T1538434634.

FDA-approved contraceptive drugs and devices, with the individual deciding the appropriate choice of method. The IFR language is overly broad, confusing, and subject to misuse and abuse by creating a federal health care framework that invites employers to refuse to participate in the orderly delivery of evidence-based health care services.

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 does not warrant ignoring basic requirements for broad public participation, even if a handful of employers 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 HHS 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 morality to object to cover women's health services.

III. 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. 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

[5] 42 U.S.C. § 18114(1).

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."[6]

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

A. Contraception Is Critical to Women's Health

Contraception and family planning are among the most well-researched and proven effective methods of preventive care.[7] They are particularly important in achieving Health People 2020's goal to "improve pregnancy planning and spacing, and prevent unintended pregnancy."[8] Access to contraception and preventive care is vital to ending health disparities that women of color face, including unintended pregnancy and high rates of cervical cancer incidence and mortality. The medical and health-related standard 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. For example, women taking Accutane for severe acne are advised to use two forms of contraception.[9] Barriers to post-partum contraception are strongly associated with poor health outcomes including very low birth weight, infant

---

[6] 2 U.S.C. § 18116.
[7] IOM, *supra* note 3.
[8] *Healthy People 2020 Topics & Objectives: Family Planning*, OFFICE OF DISEASE PREVENTION AND HEALTH PROMOTION, https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning (last visited Dec. 4, 2017).
[9] *Information for Healthcare Professionals: Isotretinoin (Marketed as Accutane)*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 2005), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm085227.htm.

mortality, and maternal mortality when women cannot ensure safe intervals between pregnancies.[10]

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

The exemptions put in place by the IFR would require employees and their dependents to take additional steps to obtain contraceptives elsewhere (*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 seek 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.[11] For this reason, research recommends that policies not only make contraceptive methods affordable, but also "simple to . . . obtain."[12] 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.

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

Cost is a significant barrier to utilization of preventive services.[13] Prior to enactment of the ACA, individuals used preventive services at about half the rate recommended by medical

---

[10] 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.

[11] *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).

[12] 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).

[13] *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

standards of care.[14] Low-income individuals and people of color used fewer preventive care services than non-Hispanic whites.[15] 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."[16] 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.[17] 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.[18] 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.[19]

Individuals pay for their health insurance through premiums and cost-sharing.[20] Cost-sharing is the portion of health care expenses not covered by the insurer that the insured must pay out-of-pocket.[21] 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).[22] The imposition of cost-sharing at the point of service is generally justified as a

---

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).

[14] 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 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").

[15] 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'SHIP FOR PREVENTION, *supra* note 14, at 7.

[16] 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.

[17] Moral Exemptions, 82 Fed. Reg. at 47,849, 47,854, *supra* note 1.

[18] RUSTGI ET AL., *supra* note 16 at 4.

[19] *Id.*

[20] DAVID MACHLEDT & JANE PERKINS, NAT'L HEALTH LAW PROGRAM, MEDICAID PREMIUMS & COST-SHARING 1 (2014), http://www.healthlaw.org/publications/search-publications/Medicaid-Premiums-Cost-Sharing#.WgCFehNSzeQ.

[21] Remler & Greene, *supra* note 13 at 294.

[22] *Id.*

means of discouraging the use of non-essential services and reducing costs, though its efficacy at achieving these goals is not established.[23]

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.[24] According to the IOM, "[s]tudies have . . . shown that even moderate copayments for preventive services . . . deter patients from receiving those services."[25] 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.[26] 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.[27] 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.[28]

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.[29] 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."[30] Another study of 11,000 employees with employer-sponsored coverage found that cost-sharing reduced use of pap smears, preventive counseling, and mammography.[31] Because the IFR

---

[23] 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.

[24] *See generally* KATHERINE SWARTZ, ROBERT WOOD JOHNSON FOUND., COST-SHARING: EFFECTS ON SPENDING AND OUTCOMES (Dec. 2010), https://www.rwjf.org/en/library/research/2011/12/cost-sharing--effects-on-spending-and-outcomes.html; Solanki et al., *supra* note 13, 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).

[25] IOM, *supra* note 3, at 19.

[26] Keeler, *supra* note 23, at 320.

[27] *Id.* at 318-19; BROOK ET AL., *supra* note 24, at 2.

[28] Kathleen N. Lohr et al., *supra* note 13, at 29.

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

[30] *Id.*

[31] Solanki et al., *supra* note 13, 1342-43; *see also* MACHLEDT & PERKINS, *supra* note 20, at 2-3.

allows employers to eliminate cost-sharing protections for their employees, it will have the effect of decreasing preventive care utilization.

D. 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.[32] It is not surprising, then, that lower-income women are the least likely to have the resources to obtain reliable methods of family planning and are the most likely to be impacted negatively by unintended pregnancy.[33]

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.[34] Studies consistently find that "[e]ven small increments in cost-sharing have been shown to reduce the use of preventive services."[35] 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."[36]

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).[37] 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%.[38]

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.[39] The study

---

[32] 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, *supra* note 3 at 109.
[33] *See* RUSTGI ET AL., *supra* note 16, 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).
[34] Liang et al., *supra* note 32, at 530-31.
[35] IOM, *supra* note 3, at 109.
[36] *Id.*
[37] Kelly Cleland et al., *Family Planning as Cost-Saving Preventive Health Service*, 364 NEW ENG. J. MED. e.37(1), e.37(2) (2011).
[38] *Id.*
[39] Jeffrey F. Peipert et al., *Preventing Unintended Pregnancies by Providing No-Cost Contraception*, 120(6) OBSTETRICS & GYNECOLOGY 1291, 1291-92 (2012).

concluded that providing no-cost contraception significantly allowed young women to avoid unintended pregnancy resulting in reduced abortion and teenage birth rates.[40] Specifically, between 2008 and 2010, the abortion rate of study participants ranged from 4.4 to 7.5 per 1,000 teens compared to the national average of 19.6 per 1,000 teens.[41] 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.[42] 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.[43] Based on their findings, the researchers estimated that providing no-cost contraception to all women would allow them to avoid unintended pregnancy and prevent as many as forty-one to seventy-one percent of abortions in the United States annually.[44] Because the IFR allows for contraceptive cost-sharing, it will reduce contraceptive use, particularly of the most effective methods.

E. 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.[45] By removing cost barriers, the ACA is proving to be effective at achieving the 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.[46] 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

---

[40] *Id.* at 1295-96.
[41] *Id.* at 1294.
[42] *Id.* The researchers "evaluated teenage birth . . . as a proxy for unintended pregnancy, as up to 80% of these births are unintended." *Id.*
[43] *Id.* at 1295-96.
[44] *Id.* at 1291-97.
[45] *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).
[46] 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.

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.[47] As rates of contraceptive coverage without cost-sharing increased, so did contraceptive access.[48] 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.[49] According to that report, oral contraceptives accounted for the largest increases in prescriptions dispensed without a copayment.[50] Reducing the cost barrier to contraception is resulting in greater access to contraception, just as the ACA intended, yet the IFR threatens those gains.

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

V. 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."[51] Allowing more entities to deprive 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

[47] *Id.* at 45-47.
[48] *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).
[49] *Id.* at 16.
[50] *Id.* at 13.
[51] 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).

> 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*."[52]

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."[53] 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."[54] 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 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' intent in maximizing the number of women who have contraceptive coverage.[55] Grandfathered plans were always expected to be phased out over time, and research shows the number of employees enrolled in such plans has in

---

[52] *Id.* at S12,027 (statement of Sen. Gillibrand) (emphases added).
[53] 155 Cong. Rec. S12,021, S12,027 (daily ed. Dec. 1, 2009).
[54] 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 . . .").
[55] *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.").

fact decreased steadily since 2010.[56] Grandfathered plans are intended as a temporary means for transitioning employers to full-compliance plans.[57] 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."[58] 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.[59] Indeed the number of employer-sponsored grandfathered plans has decreased steadily since the ACA's enactment.[60] 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.[61]Additionally, federal statutes "often include exemptions for small employers, and such provisions have never been held to undermine the interests served by these statutes."[62]

VI. The Terms of the Regulation Are Unconstitutionally Vague and Ambiguous

[56] 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.

[57] 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 56; Collins, *supra* note 56; Levitt, *supra* note 56; Barr, *supra* note 56; Leonard, *supra* note 56.

[58] *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 56.

[59] Leonard, *supra* note 56.

[60] CLAXTON ET AL., *supra* note 56.

[61] *Id.*

[62] *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).

The Due Process clause of the Fifth Amendment to the U.S. Constitution provides that "[n]o person shall . . . be deprived of life, liberty, or property, without due process of law." It is well-established that the Due Process clause requires that "laws which regulate persons or entities must give fair notice of conduct that is forbidden or required."[63] Because the IFR fails to give employees fair notice of the standard of morality that will be used to determine whether to grant a moral exemption, it violates Due Process.[64]

The IFR authorizes almost any employer or institution to opt out, in full or in part, of the contraceptive coverage requirement, but is silent as to what constitutes a sincerely held moral conviction. Can a Chief Operations Officer decide unilaterally that the employer has an objection to contraception? Does the Board of Directors need to vote? Does the employer need to have had a previous moral objection to contraception, or can it "develop" a sincerely held moral conviction now that there is the ability to opt out? The regulation does not say, and reasonable people could interpret it in a multitude of ways. The IFR leaves people "of common intelligence [to] necessarily guess at its meaning and differ as to its application," and thus violates Due Process.[65]

The IFR is also void for vagueness, and thus violates Due Process, because it "is so standardless that it authorizes or encourages seriously discriminatory enforcement."[66] In *Grayned v. City of Rockford*, the Supreme Court determined that a law must provide "explicit standards" to law enforcement officials, judges, and juries.[67] When a rule describes a specific exemption, the enforcer of the rule must know what to look for to determine whether the rule is violated. The IFR, by contrast, gives federal agencies no guidance as to what to look for in determining whether the rule is violated. The administration claims that "[t]he mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held moral convictions, is a matter of well-established State law," but does not cite to any such well-established laws. While some state laws provide "moral" exemptions for health care providers in certain contexts (such as participation in an abortion procedure), all states do not have well-established laws that define corporate morality.[68] Even if these laws were well-established and easily accessible, they would result in a patchwork of outcomes, whereby a national employer could have a sincerely held moral objection to contraception for employees in one state or locality, but

---

[63] F.C.C. v. Fox Television Stations, Inc., 132 S. Ct. 2307, 2317-18 (2012).
[64] 45 C.F.R. § 147.133(a), provides, in pertinent part, as follows:

> (2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

[65] Connally v. Gen. Constr. Co., 269 U.S. 385, 391 (1926).
[66] United States v. Williams, 553 U.S. 285, 304 (2008).
[67] 408 U.S. 104 (1972).
[68] *Refusing to Provide Health Services*, GUTTMACHER INSTITUTE (Dec. 2017), https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services.

not in others. The result is a lack of meaningful guidance to potential violators, regulators, or woman employees as to what conduct is prohibited.

This vagueness is even more concerning because the IFR contains no mechanism for the federal government to provide oversight and ensure appropriate coverage. A company that wants to take advantage of the exemption need not certify that its owners have a moral objection to contraception. It merely needs to drop or omit contraception coverage from its plan's terms and comply with other applicable law. Neither states nor the federal administration will have notice of which employers or institutions are utilizing the exemption; the onus is on the affected woman to read her benefits notice, question her employer about the specific moral beliefs behind this decision (although the employer has no affirmative duty to respond), and then litigate if she believes the moral belief is capricious. This creates the opportunity for arbitrary and discriminatory enforcement in violation of the Due Process clause.

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

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.[69] 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 patients. 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 and Do Not Have Capacity to Do So

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. Title X is the nation's only dedicated source of federal funding for family planning services, and federal law requires Title X-funded health centers to give priority to "persons from low-income families."[70] Low-income individuals receive services at these health centers at low or no cost depending on their family income.[71] Furthermore, Congress did not design Title X as a substitute for

[69] Moral Exemptions, 82 Fed. Reg. 47,838, *supra* note 1.
[70] *See* Fam. Plan. Servs. & Population Res. Act of 1970, Pub. L. No. 91-572, 84 Stat. 1504, and 42 CFR § 59.5 (a)(6-9).
[71] 42 U.S.C. § 300a-4(c)(2); 42 C.F.R. § 59.5(a)(7)-(8).

employer-sponsored coverage. The Title X statute and regulations contemplate how Title X and third-party payers, including employer-sponsored coverage, will work together to pay for care, directing Title X-funded agencies to seek payment from such third-party payers.[72]

The IFR argues that Title X-funded health centers could fill the gap in contraceptive coverage it creates, and provide 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. Requiring otherwise higher-income, privately insured individuals to use Title X-funded health centers would deplete resources from an already overburdened and underfunded program.

Similarly, 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.[73] 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.

Medicaid enrollees have robust access to health care, including family planning services and supplies, 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.[74] This is particularly true with respect to specialty providers, including OB/GYNs.[75] Given this provider shortage and Medicaid's eligibility requirements discussed above,

---

[72] 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 CFR § 59.5(a)(7), (9).

[73] 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 that have not expanded Medicaid, childless adults remain ineligible for this program. RACHEL GARFIELD & ANTHONY DAMICO, KAISER FAMILY FOUNDATION, 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/.

[74] *States Made Multiple Program Changes, and Beneficiaries Generally Access Comparable to Private Insurance*, U.S. GOVERNMENT ACCOUNTABILITY OFFICE (Nov. 2012), http://www.gao.gov/assets/650/649788.pdf; Office of Inspector General, *Access to Care: Provider Availability in Medicaid Managed Care*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Dec. 2014), http://oig.hhs.gov/oei/reports/oei-02-13-00670.pdf.

[75] 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. Office of Inspector General, *supra* note 74.

Medicaid does not have capacity to serve individuals who lose coverage as a result of this IFR.

Furthermore, 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.[76] 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.[77] These waivers may very well include provisions that undermine the ability of individuals qualified to enroll in Medicaid to receive the coverage and health care they need. Finally, Congress and the Trump Administration have threatened women's health by attempting to block Planned Parenthood from participating in Medicaid despite the outsized role that Planned Parenthood plays in delivering family planning care to people with Medicaid coverage. In fact, in 57 percent of counties with a Planned Parenthood health center, Planned Parenthood serves at least half of all safety-net family planning patients with Medicaid coverage.[78] These dangerous proposals would severely limit access to high-quality family planning care for individuals enrolled in the Medicaid program, including low-income and uninsured women, LGBTQ individuals, communities of color, and young people.

For these reasons, Title X and Medicaid will not be real alternatives for securing contraceptive care and counseling for those women who will lose access.

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

---

[76] 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, *Top 10 Changes to Medicaid Under the Graham-Cassidy Bill*, NAT'L HEALTH LAW PROGRAM (Sept. 14, 2017), http://www.healthlaw.org/publications/browse-all-publications/top-10-changes-to-medicaid-under-graham-cassidy-bill#.Wft9mmhSzIV.

[77] 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*, 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.

[78] Kinsey Hasstedt, Understanding Planned Parenthood's Critical Role in the Nation's Family Planning Safety Net, GUTTMACHER POLICY REVIEW (2017), https://www.guttmacher.org/gpr/2017/01/understanding-planned-parenthoods-critical-role-nations-family-planning-safety-net.

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.[79]

The major reason that state laws are insufficient is because they are preempted as applied to employers that provide self-insured health coverage; under the Employee Retirement Income Security Act of 1974 ("ERISA"), only Congress can regulate the benefits in 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.[80] 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.[81] 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.[82]

VIII. The Departments' Proposed Changes to the Rule Do Not Fix the Above Problems

The Departments request comment on several ways the IFR could be changed to expand exemptions to the birth control benefit, such as making it available to publicly traded for-profit companies. Each of the questions presented by the Departments is based on an assumption that the IFR is legally sound, and in some instances, that it should be expanded. As described in detail above, this assumption is incorrect and NHeLP strongly objects to any expansion of the exemption and/or accommodation. Other than completely striking it, there is nothing the Departments could do to make this better, and any expansion would only further violate the law.

---

[79] *Insurance Coverage of Contraceptives*, GUTTMACHER INSTITUTE (Dec. 2017), http://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.

[80] CLAXTON ET AL., *supra* note 56, at 162.

[81] *Contraceptive Equity Laws in Your State: Know Your Rights – Use Your Rights, A Consumer Guide*, NATIONAL WOMEN'S LAW CENTER (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.

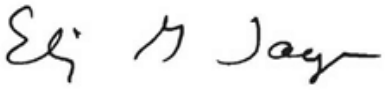
[82] For example, only three states currently require coverage of female sterilization, and only two states currently require coverage of methods sold over the counter (such as some types of emergency contraception). Several additional states have enacted new requirements that will take effect in 2018 or 2019. *See Insurance Coverage of Contraceptives*, *supra* note 79.

IX. Conclusion

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 make this necessary service inaccessible for millions of women. We strongly object to the expanded exemptions and accommodations in the IFR that prioritize the "moral" opinions of a few over the evidence-based public health of women. We urge the Department 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 Susan Berke Fogel, Reproductive Health Director, at fogel@healthlaw.org.

Respectfully Submitted,



Elizabeth G. Taylor
Executive Director