

December 5, 2017

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016
Attention: CMS-9940-IFC



Submitted electronically at www.regulations.gov

Subject: Interim Final Rule on Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act [CMS-9940-IFC]



The National Partnership for Women & Families, Jacobs Institute of Women's Health, and Union of Concerned Scientists submit the following comments in response to the Interim Final Rules ("the Rules") titled "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act"¹ and "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act,"² published in the Federal Register on October 13, 2017, by the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services ("the Departments").

Our organizations work to ensure that U.S. policy decision-making is fully informed by scientific evidence and the best available data, and that the public has reliable access to independent scientific information and analysis produced and acquired by the federal government. The role of scientific evidence in public health decision-making is imperative, and we oppose any efforts to diminish the role of science in federal policymaking.

Unfortunately, the Rules are a prime example of regulatory decision-making that ignores scientific evidence and the best available data. The Departments' summary of the evidence is arbitrary and cherry-picked. The Departments understate the efficacy and health benefits of contraceptives and overstate the health risks of contraceptives by selectively interpreting data, overlooking well-established evidence, and promoting unfounded doubt. Further, both Rules falsely assert certain types of FDA-approved contraceptive methods to abortifacients.

The Rules thus cause dual harm by undermining women's access to essential preventive health care and undermining the integrity of science in governance. Public health policy should be informed by the best available scientific evidence. Instead, the Departments use false claims about contraception that are contrary to medical and public health evidence, misstate or ignore research, and undermine the agencies' role as a source of accurate health information.

The Departments serve a critical role in collecting and managing important information and data on issues that are vital to the public. In making policy, it is essential that the Departments enhance their credibility on issues of science and evidence, not undermine it. Thus, the

Departments must take full advantage of their resources to inform their decision-making by the best available evidence and data. The Rules, however, show that the Departments did not seriously consider these elements, which can only undermine the Departments' reputations as reliable sources of information.

Below we outline several ways the Rules are at odds with science and research. We urge the Departments to withdraw both Rules.

Contraception Prevents Unintended Pregnancy and Improves the Health of Women and Children

As an example of how the Departments are not utilizing the best available science and evidence with dire consequences for public health, the Departments make several misstatements that ignore prevailing evidence regarding the efficacy, health benefits, and health risks of contraceptives. First, the Departments fail to acknowledge that contraceptive efficacy in preventing unintended pregnancy is well established and supported in evidence.³ Second, the Departments falsely associate several health risks with contraceptive use, ignoring the weight of the evidence.⁴ The Departments' summary of the evidence is wrong and misleading. Not only does contraception prevent unintended pregnancy,⁵ but the prevention of unintended pregnancy is associated with life-long health benefits for both women and children that the Departments fully ignore. Further, the Departments' overstatement of health risks ignores the long, evidence-based list of non-contraceptive health benefits associated with contraceptives.

Contraceptive efficacy at preventing unintended pregnancy is supported by decades of rigorous evidence and by the government itself.⁶ The U.S. Food and Drug Administration ("FDA") must approve all new drugs and devices by showing that they are safe and effective through rigorous scientific testing. The federal government itself has thus approved contraceptives for safely and effectively preventing unintended pregnancies.⁷ The Departments' misrepresentation of "complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy"⁸ is false and relies heavily on cherry-picked citations instead of accurately reflecting the weight of the evidence. For instance, the Departments point to a single pre-ACA economics paper positing that contraceptive use may be connected to an increase in teen pregnancy over the "long run."⁹ This paper utilized 1997 youth survey data where the majority of respondents were using condoms or another "episodic" form of birth control,¹⁰ the efficacy of which is irrelevant to an assessment of the efficacy of the methods of birth control covered under the ACA's contraceptive benefit, and hardly contributes to "uncertainty"¹¹ regarding decades of clinical data that prove otherwise.

In truth, contraception enables women, including teens, to prevent unintended pregnancy and control the timing of a desired pregnancy.¹² The Centers for Disease Control and Prevention named family planning one of the ten great public health achievements of the past century,¹³ and family planning is widely credited for contributing to women's societal, educational, and economic gains.¹⁴ The ACA's guarantee of no-copay coverage of contraception has contributed to a dramatic decline in the unintended pregnancy rate in the United States, now at a 30-year low.¹⁵ The teen pregnancy rate is also at the lowest point in at least 80 years.¹⁶

Contraception improves health outcomes for women and children because unintended pregnancies have higher rates of short- and long-term health complications. Women with unintended pregnancies are more likely to delay prenatal care, leaving their health complications

unaddressed.¹⁷ They are also at increased risk of maternal mortality and morbidity, maternal depression, experiencing physical violence during pregnancy,¹⁸ infant mortality, birth defects, low birth weight, and preterm birth.¹⁹ Unintended pregnancies are also associated with long-term negative physical and mental effects on children.²⁰ Contraception, by contrast, is considered a major factor in reducing rates of maternal mortality and morbidity. For example, a study of 172 developing countries found that use of contraception is an “effective primary prevention strategy to reduce maternal mortality”²¹ The Departments’ new Rules paper over this vast body of research and the clear health benefits of contraception.

The Health Risks of Contraceptives Are Overstated and Misrepresented

The Departments go further, selectively interpreting data in order to overstate “negative health effects” associated with contraceptives.²² This includes misleading assertions of an association between contraceptive use, breast cancer, and cervical cancer, as well as vascular events and “risky sexual behavior.”²³ The Departments ignore substantial evidence to the contrary, and ignore the balance of significant non-contraceptive health benefits associated with contraceptive use. Certainly it is true that, as with any medication, some types or methods of contraception may be contraindicated for patients with certain medical conditions, including high blood pressure, lupus, or a history of breast cancer.²⁴ Some women may also want to avoid side effects such as changes to menstrual flow.²⁵ But the Departments fail to recognize that this means that patients and health care providers, not employers and agencies, should determine the right contraceptive for an individual woman’s health care needs.

The Departments’ claim that contraceptive use is associated with an increased risk of breast and cervical cancers is based solely on a 2013 Agency for Healthcare Research and Quality report, when in fact the evidence is not decisive, and to say so is a misrepresentation. There is no proven increased risk of breast cancer among contraceptive users, particularly those under 40. For women over 40, health care providers must consider both the risks of becoming pregnant at an advanced reproductive age, as well as the risks of continuing contraception use until menopause, making it essential that a woman be able to discuss options with her provider without interference.²⁶ And, on the topic of cervical cancer, the Departments cite only a study on oral contraceptives, when a recent study found that intrauterine devices (“IUDs”) are associated with a decreased risk of cervical cancer.²⁷

It is especially irresponsible to misrepresent the risks of breast and cervical cancer without accurately reporting the substantial evidence of contraceptives’ association with cancer prevention, since any evaluation of preventive health care should fully weigh the risks and benefits.²⁸ Contraceptives are associated with a reduced risk of colorectal cancer;²⁹ endometrial cancer is 50 percent less likely among women who use oral hormonal contraceptives for at least one year compared to women who have never used oral hormonal contraceptives;³⁰ oral hormonal contraceptives can reduce the risk of ovarian cancer by 27 percent, and 20 percent for every five years of additional use;³¹ oral hormonal contraceptives can lower the risk of hereditary ovarian cancer in women with the BRCA1 or BRCA2 gene mutations;³² and oral hormonal contraceptive use for more than 10 years can lower the risk of ovarian cancer among women with endometriosis, who are typically at higher risk of developing ovarian cancer.³³

The Rules also incorrectly suggest that contraceptive use is connected to an increased risk of “vascular events” such as venous thromboembolism (“VTE”). The risk of VTE among oral contraceptive users is very low.³⁴ In fact, it is much lower than the risk of VTE during pregnancy

or in the immediate postpartum period, so prevention of unintended pregnancy actually reduces women's risk of VTE.³⁵

The Departments' claim that contraceptives may lead to "risky sexual behavior"³⁶ is similarly unfounded. Increased access to contraception is not associated with a change or increase in sexual behaviors.³⁷ Instead, research has shown that 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.³⁸ In the "CHOICE Project," a large-scale U.S. study aimed at reducing unintended pregnancy by providing no-cost contraception, participants reported no change in their sexual activities after receiving contraceptives.³⁹

Contraceptives are also associated with other non-contraceptive health benefits beyond the cancer prevention benefits listed above. Benefits include reduced menstrual pain, reduced risk of myoma, reduced symptoms of endometriosis, and reduced symptoms of premenstrual syndrome and premenstrual dysphoric disorder.⁴⁰ Oral hormonal contraceptives have been found to reduce the risk of pelvic inflammatory disease by 50 to 60 percent,⁴¹ Contraceptives are also associated with lower risk of rheumatoid arthritis, preservation of bone density, and reduced symptoms of asthma.⁴²

In sum, the Departments overstate the evidence of health risks and understate the evidence of contraceptive efficacy and health benefits, failing to accurately reflect the weight of evidence that shows that contraceptives are associated with a variety of short- and long-term health benefits, improving health outcomes for both women and children. And the various contraindications associated with some forms of birth control actually support the opposite finding: women should have access to the full range of FDA-approved methods and must be able to work with health care providers to choose the method that best suits their health concerns and needs without interference from an employer.

Contraceptives Do Not Interfere with an Existing Pregnancy

Both Rules refer to the false assertion that some FDA-approved methods of contraception "prevent implantation of an embryo," and are thus abortifacients.⁴³ This is inaccurate and goes against longstanding medical evidence.

Policies that restrict women's access to preventive health care should not be based on falsehoods that are not supported by science, regardless of who "believes" them. 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."⁴⁴ 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, which is when pregnancy begins.⁴⁵

By making the false claim that some FDA-approved methods of contraception may cause abortion, the Departments sideline science in favor of ideology.

The Rules Should Be Withdrawn Because They Are Based on Falsehoods, Undermine Scientific Integrity, and Harm Women’s Health

For the reasons stated above, the National Partnership for Women & Families, Jacobs Institute of Women’s Health, and Union of Concerned Scientists object to the Interim Final Rules titled “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” and “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act.” The Rules should be withdrawn due to their lack of scientific basis and their harmful impact on women’s health and economic security.

¹ Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).

² Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).

³ See generally American College of Obstetricians and Gynecologists. (2016, December). *Women’s Preventive Services Initiative: Recommendations for Preventive Services for Women Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration* (p. 82–91). Retrieved 27 November 2017, from <https://www.womenspreventivehealth.org/final-report/>. See also Trussell, J. (2011, May). Contraceptive failure in the United States. *Contraception*, 83(5), 397–404; Finer, L.B., & Zolna, M.R. (2016, March). Declines in unintended pregnancy in the United States, 2008–2011. *New England Journal of Medicine*, 374(9), 843–852.

⁴ Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,804–05 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).

⁵ See, e.g., Finer, L.B., & Zolna, M.R. (2016, March). Declines in unintended pregnancy in the United States, 2008–2011. *New England Journal of Medicine*, 374(9), 843–852 (“A likely explanation for the decline in the rate of unintended pregnancy is a change in the frequency and type of contraceptive use over time.”).

⁶ See, e.g., Institute of Medicine. (2011). *Clinical Preventive Services for Women: Closing the Gaps*. Washington, DC: The National Academies Press; American College of Obstetricians and Gynecologists. (2016, December). *Women’s Preventive Services Initiative: Recommendations for Preventive Services for Women Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration* (p. 82–91). Retrieved 27 November 2017, from <https://www.womenspreventivehealth.org/final-report/>; Trussell, J. (2011, May). Contraceptive failure in the United States. *Contraception*, 83(5), 397–404; Hatcher, R.A., Trussell, J., Nelson, A.L., Cates, W., Kowal, D., & Policar, M.S. (Eds.). (2011). *Contraceptive Technology* (20th ed.). Atlanta, GA: Bridging the Gap Communications; Declaration of Dr. Lawrence Finer in Support of Plaintiffs’ Motion for Preliminary Injunction at 4–5, *California v. Wright*, No. 4:17-cv-05783-HSG (Nov. 9, 2017) (“Sexually active couples using no method of contraception have a roughly 85% chance of experiencing a pregnancy in a one-year period, while the risk for those using a contraceptive method ranges from 0.05% to 28%.”) (citing Sundaram, A., Vaughan, B., Bankole, A., Finer, L., Singh, S., & Trussell, J. (2017, March). Contraceptive failure in the United States: Estimates from the 2006–2010 National Survey of Family Growth. *Perspectives on Sexual and Reproductive Health*, 49(1), 7–16); Peipert, J.F., Madden, T., Allsworth, J.E., & Secura, G.M. (2012, December). Preventing unintended pregnancies by providing no-cost contraception. *Obstetrics & Gynecology*, 120(6), 1291–1297; Finer, L.B., & Zolna, M.R. (2016, March). Declines in unintended pregnancy in the United States, 2008–2011. *New England Journal of Medicine*, 374(9), 843–852; Harper, C.C., Rocca, C.H., Thompson, K.M., Morfesis, J., Goodman, S., Darney, P.B., . . . Speidel, J.J. (2015, June). Reductions in pregnancy rates in the USA with long-acting reversible contraception: A cluster randomised trial. *The Lancet*, 386(9993), 562–568; Speidel, J.J., Harper, C.C., & Shields, W.C. (2008, September). The potential of long-acting reversible contraception to decrease unintended pregnancy. *Contraception*, 78(3), 197–200.

⁷ Declaration of Dr. Lawrence Finer in Support of Plaintiffs’ Motion for Preliminary Injunction at 5, *California v. Wright*, No. 4:17-cv-05783-HSG (Nov. 9, 2017).

⁸ Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,804 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147).

⁹ Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,804 (Oct. 13, 2017) (to be codified at 26 C.F.R. pt. 54, 29 C.F.R. pt. 2590, 45 C.F.R. pt. 147) (citing Arcidiacono, P., Khwaja, A., & Ouyang, L. (2005). *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* Available at <http://public.econ.duke.edu/~psarcidi/teensex.pdf> [sic]).

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- ¹⁰ Arcidiacono, P., Khwaja, A., & Ouyang, L. (2011, January 22). *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* Retrieved 27 November 2017, from <http://public.econ.duke.edu/~psarcidi/teensex.pdf>
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- ¹⁹ Orr, S.T., Miller, C.A., James, S.A., & Babones, S. (2000, October). Unintended pregnancy and preterm birth. *Paediatric and Perinatal Epidemiology*, 14(4), 309–313; Conde-Agudelo, A., Rosas-Bermúdez, A., & Kafury-Goeta, A.C. (2006). Birth spacing and risk of adverse perinatal outcomes: A meta-analysis. *JAMA*, 295(15), 1809–1823. See also Goldthwaite, L.M., Duca, L., Johnson, R.K., Ostendorf, D., & Sheeder, J. (2015, September). Adverse birth outcomes in Colorado: Assessing the impact of a statewide initiative to prevent unintended pregnancy. *American Journal of Public Health*, 105(9), e60–e66 (establishing an association between use of long-acting reversible contraception and a lower risk of preterm birth).
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- ²¹ Ahmed, S., Li, Q., Liu, L., & Tsui, A.O. (2012, July). Maternal deaths averted by contraceptive use: An analysis of 172 countries. *The Lancet*, 380(9837), 111–125.
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- ⁴⁴ Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,749 (Oct. 13, 2017).
- ⁴⁵ See, e.g., Brief of *Amici Curiae* Physicians for Reproductive Health, et al. in Support of Petitioners at 12, *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. ___, 134 S. Ct. 2751 (2014) (No. 13-354).