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COMMENTS OF THE SEX AND LAW COMMITTEE REGARDING NEW YORK STATE DEPARTMENT OF FINANCIAL SERVICES PROPOSED RULE MAKING: ADDITION OF SECTIONS 52.17(A)(36), (37), 52.18(A)(11) AND (12) TO TITLE 11 NYCRR

The Sex and Law Committee of the New York City Bar Association is grateful for the opportunity to provide comments to the Department of Financial Services regarding the addition of sections 52.17(a)(36), (37), 52.18(a)(11) and (12) to Title 11 New York Codes, Rules & Regulations (NYCRR), clarifying that insurance policies are required to include at least one form of contraception within each of the Food and Drug Administration's (FDA) approved methods without co-payments; and allowing for the dispensing of an entire prescribed supply of contraceptives up to 12 months.[1]

The Sex and Law Committee of the New York City Bar Association addresses issues pertaining to gender and the law in a variety of areas that aim to reduce barriers to gender equality in health care, the workplace and civic life and to promote respect for the rule of law. The Committee's members work and practice in a wide range of areas, including, violence against women, reproductive rights, gender discrimination, poverty, matrimonial and family law, employment law, and same-sex marriage. In light of the Committee's long history and expertise in promoting gender equality and defending constitutional rights, we are uniquely positioned to submit comments on the proposed sections.

The Sex and Law Committee commends the Department for clarifying that insurance policies must include at least one form of contraception within each of the FDA's approved methods without co-payments. However, we strongly recommend these requirements be strengthened to include all forms of contraceptives and necessary counseling services to fully meet the reproductive health needs of the men and women of New York. The Sex and Law Committee further supports the Department's proposed rule for allowing for the dispensing of an entire prescribed supply of contraceptives up to 12 months; however, we urge several changes to ensure the rule effectively removes barriers to consistent contraceptive use.

[1] Katharine Bodde, Alyson Zureick, and Hillary Schneller of the Sex & Law Committee were the primary drafters of these comments, which draw from model comments issued by the New York Civil Liberties Union.

CONTRACEPTION SERVICES ARE ESSENTIAL FOR WOMEN'S HEALTH AND EQUALITY

First approved by the FDA over 50 years ago, contraception has significantly transformed the cultural landscape in the United States. By providing women[2] the tools and agency to determine whether and when to have children, contraception has been a catalyst for women's equal participation in our political and educational institutions as well as the paid workforce. The United States Supreme Court has held that if personal liberty "means anything, it is the right of the individual, married or single, to be free from unwarranted government intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[3] Moreover, the Court has recognized that efforts to make contraceptives less accessible may infringe on this fundamental right.[4]

Beyond these fundamental cultural shifts that give way to equal participation, contraception provides essential health benefits that are both related and unrelated to managing fertility. Indeed, contraception leads to improved birth outcomes and child health, reductions in morbidity and mortality rates and decreases in the risk of developing several reproductive cancers.[5]

While 99% of sexually active women of reproductive age use or have used contraception at some point in their lives,[6] lack of comprehensive contraceptive insurance coverage and high co-payments are significant barriers to consistent and effective contraceptive use. Fifty percent of pregnancies in the United States are unintended; of these, about half are due to a lack of contraceptive use and most of the other half are a result of inconsistent or incorrect contraceptive use.[7] In 2010, 55% of all pregnancies in New York were unintended, and the state stood to save $448 million if these unintended pregnancies had been prevented.[8]

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[2] Not all people who seek contraception identify as women. While the comments here reference "women" and "female" they are meant to capture all who seek this care, including, but not limited to, transgender men.

[3] *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

[4] *Carey v. Population Services International*, 431 U.S. 678 (1977) (holding unconstitutional limiting distribution of contraceptives to licensed pharmacists because it would make contraceptives less accessible and reduced price competition).

[5] Megan Kavanaugh & Ragnar Anderson, *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Center*, Guttmacher Institute (2013), https://www.guttmacher.org/sites/default/files/report_pdf/health-benefits.pdf.

[6] Kimberly Daniels, William D. Mosher, & Jo Jones, *Contraceptive Methods Women Have Ever Used: United States, 1982-2010*, U.S. Centers for Disease Control and Prevention. National Health Statistics Report no.62 (2013), https://www.cdc.gov/nchs/data/nhsr/nhsr062.pdf (finding that 99 percent of sexually active women of reproductive age in 2006–2010 who had ever had sexual intercourse have used at least one contraceptive method at some point in their lifetime).

[7] *Contraception and Beyond: The Health Benefits of Services Provided at Family Planning Centers*, *supra* note 4.

[8] Adam Sonfield, & Kathryn Kost, *Public Costs from Unintended Pregnancies and the Role of Public Insurance Programs in Paying for Pregnancy-Related Care: National and State Estimates for 2010*, Guttmacher Institute (2015), http://www.guttmacher.org/pubs/public-costs-of-UP-2010.pdf.

ADDITIONS TO TITLE 11 NYCRR CLARIFY INSURANCE PLANS MUST COVER CONTRACEPTION WITHOUT A CO-PAYMENT, AND ALLOW FOR DISPENSING OF A 12-MONTH SUPPLY

Improving access to contraception is critical to the health and wellbeing of our families and communities. New York has recognized this since 2002, when the Women's Health and Wellness Act (WHWA) was passed, requiring insurance plans issued in New York that cover prescription drugs to include all FDA approved contraceptive drugs and devices.[9] In 2010 the federal government, recognizing the role that lack of insurance coverage or high copayments play in placing barriers to women's access to contraception, passed the federal Patient Protection and Affordable Care Act (ACA) and promulgated implementation guidelines which require insurance plans to cover at least one form of contraception within each of the FDA approved methods without co-payments.[10]

While these laws represent significant dedication by the state and federal government to improving access to contraception, they have not been enough to close the contraception coverage gap. While the ACA requires contraceptive coverage without a co-payment, it does not require coverage of the full array of contraceptive types available within each of the FDA's approved methods. This means that women may still not be able to afford the form of contraception that's best for them, and men are left out of the coverage requirements entirely. Further, a lack of clarity in the federal law has led to inconsistent implementation and enforcement here in New York. In the spring of 2014, the New York Alliance for Women's Health ("NYAWH"), based on research that included "secret shopper" calls its members made to insurance plans, concluded that plans that insurers were offering in the NYS Health Exchange were inappropriately charging cost-sharing and omitting coverage of some methods of contraception, putting women at risk of unintended pregnancy. A follow-up series of calls by NYAWH in January and February of 2016 found that many of these problems continue to exist. In a letter to the NYS Department of Financial Services dated March 1, 2016, leaders of NYAWH called on DFS to investigate and take action to address the failure of health plans to comply with the ACA's contraceptive coverage requirements. A recent report by the Department released in February of 2017 found that 75 percent of surveyed plans were out of compliance with the coverage requirements.[11]

Moreover, the current protections for women in New York are shaped by and rely on federal law and guidance, and are vulnerable to shifts in guidelines and enforcement of the current law, as well as any potential repeal of the ACA or rescission of FDA or HHS guidance.

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[9] N.Y. Ins. Law § 3221 (l)(16) (requiring all federal Food and Drug Administration approved contraceptive services including oral contraceptives, diaphragms, Norplant, Depo Provera, cervical caps, IUDs and generic equivalents).

[10] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 199 (2010); 42 U.S.C.A. § 300gg–13(a)(4) (in accordance with the ACA and implementing regulations, the Department of Health and Human Services issued *Women's Preventive Services: Required Health Plan Coverage Guidelines*, which adopt the independent Institute of Medicine evidence-based recommendations, and require coverage of eight preventive health care services, including all FDA-approved methods of contraception, without cost-sharing. The guidelines and a list of covered preventive health care services for women are available at http://www.hrsa.gov/womensguidelines/.

[11] New York State Department of Financial Services, *Health Plan Non-Compliance on Contraceptive Coverage in New York* (2017), http://www.dfs.ny.gov/reportpub/contraceptive_coverage_rpt_022017.pdf.

There is confusion at the federal level around the future of the health care law, and the new presidential administration and Congress have communicated an intention to repeal the ACA and dismantle the federal contraceptive coverage requirement.[12] If the ACA is repealed and the contraceptive requirement rescinded, without state action New York's insurers would no longer be required to cover contraception without co-payments, potentially forcing many individuals to choose less reliable methods of contraception or no contraception at all. In these times, New York should be moving in a direction that protects access to women's health care.

New York needs to strengthen and interpret existing protections to close current loopholes so that all families have access to affordable contraceptive coverage. On February 8, 2017 the Department of Financial Services published a proposed rule adding sections 52.17(a)(36), (37), 52.18(a)(11) and (12) to Title 11 NYCRR. These sections clarify that insurance policies are required to include at least one form of contraception within each of the FDA's approved methods without co-payments; and allow for the dispensing of an entire prescribed supply of contraceptives up to 12 months subsequent to the dispensing of an initial three-month supply. The Sex and Law Committee supports the proposed rule and applauds the Department for recognizing the centrality of contraception care to women's health and lives. We make several recommendations to ensure the proposed rule effectively removes barriers to contraceptive insurance coverage.

1. **The Department should broaden the category of contraceptives covered without a co-payment to include the full range of FDA approved methods and types of contraception.**

As proposed, the rule clarifies that New York law: 1) requires policies and contracts that provide prescription drug coverage to provide coverage for all contraceptive drugs and devices approved by the FDA or generic equivalents as required by the WHWA; and 2) requires every policy or contract delivered or issued for delivery in New York that provides hospital, surgical, or medical care coverage to provide coverage for certain preventive care and screenings, including contraceptives, at no cost-sharing. With respect to the latter requirement, under the Department's authority to issue regulations establishing minimum standards, the proposed rule adopts a standard reflecting the current federal standards under the ACA that requires insurers to cover at least one form of contraception within each of the 18 methods of contraception that the FDA has identified for women without co-payments.[13] We strongly recommend broadening the

[12] Michael Shear, *Trump Promises 'Insurance for Everybody' as Health Law Replacement*, The New York Times (Jan. 15, 2017), https://www.nytimes.com/2017/01/15/us/politics/trump-health-law-replacement.html.

[13] 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130; Departments of Labor, Department of Treasury, Health and Human Services, FAQS About Affordable Care Act Implementation,(May 11, 2015), https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/aca_implementation_faqs26.pdf (The contraceptive methods for women currently identified by the FDA include: (1) sterilization surgery for women; (2) surgical sterilization implant for women; (3) implantable rod; (4) IUD copper; (5) IUD with progestin; (6) shot/injection; (7) oral contraceptives (combined pill); (8) oral contraceptives (progestin only); (9) oral contraceptives extended/continuous use; (10) patch; (11) vaginal contraceptive ring; (12) diaphragm; (13) sponge; (14) cervical cap; (15) female condom; (16) spermicide; (17) emergency contraception (Plan B/Plan B One Step/Next Choice); and (18) emergency contraception (Ella). The FDA Birth Control Guide additionally lists sterilization surgery for men and male condoms, but the HRSA Guidelines exclude services relating to a man's reproductive capacity).

category of contraceptives without a co-payment to reflect the standard in the WHWA, which would require policies and contracts to provide coverage without co-payments for the full range of contraceptive drugs and devices approved by the FDA or generic equivalents, and to include coverage of male contraceptives without a co-payment. Furthermore, we urge the Department to clarify that coverage for necessary associated services such as counseling, insertion, and removal is required under these standards.

Although a huge step forward, the ACA's requirement that insurance plans cover at least one form of contraceptive within each method still leaves many women without access to the birth control that is best for them. Many different types of contraception exist within the FDA's 18 categories. For instance, there are 33 different types of birth control pills within the oral contraceptive method of contraception, each type with varying hormonal levels and corresponding degrees of medical appropriateness for the individual patient. Contraception is not a one-size-fits-all model. A variety of contraception types within each method exist because not all forms of contraception are effective or appropriate for a specific woman's health and her lifestyle. Dissatisfaction with one's contraception is associated with incorrect or inconsistent contraception usage, which leads to nearly half of all unintended pregnancies.[14] While ensuring one type from each FDA method is covered without a co-payment is a good baseline standard, establishing a requirement that insurers cover the full array of contraceptives currently FDA approved (or their therapeutic and pharmaceutical equivalents) would guarantee the coverage patients need to access the type of contraception that is medically best for them.

To avoid coverage gaps, the Department proposes an exceptions process that would allow patients to access any contraceptive without a co-payment where it is deemed medically necessary; this exceptions process replicates a similar approach taken by HHS at the federal level. However, exceptions processes have proven to be unduly burdensome on the individual and the provider, resulting in gaps in use and risk of unintended pregnancy. This process requires individuals to understand both the requirement and the process for contacting their insurance company to request an exception, and causes significant delays in accessing their contraception, potentially leaving them without any contraception during the wait. Requiring all types within each method to be covered avoids the inherent delays of an exceptions process and ensures that providers are best able to help patients make health care decisions about their contraception that are right for their health and their lives.[15] Plans and issuers may still use reasonable medical management techniques to control costs and promote efficient delivery of care, such as covering a generic drug without cost sharing and imposing cost sharing for equivalent branded drugs.

All forms of contraception provide a significant cost savings to payers; a review by the Guttmacher Institute found that studies have consistently shown that all forms of contraception

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[14] J.J. Frost et al., *Improving Contraceptive Use in the United States*, Guttmacher Institute (2008).

[15] The NYAWH's March 1, 2016 letter to DFS noted that several health plans sold in the NYSOH marketplace did not have descriptions of their exceptions process readily available to consumers, either on website or through customer service representatives. If the Department elects to maintain a narrow contraceptive coverage requirement, we recommend including guidance within the proposed rule that ensures that an insurers exception process is easily accessible, transparent, and sufficiently expedient. *See*, e.g. FAQS About Affordable Care Act Implementation (May 11, 2015), https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/aca_implementation_faqs26.pdf.

are cost-effective for both public and private payers.[16] Publicly funded contraception has been consistently proven to save money: in 2008 the federal Medicaid program saved $3.74 for every dollar spent on contraception, and similar savings have been found in state Medicaid programs.[17] In 2000 a study by the National Business Group on Health, a membership group for large private and public sector employers to address their health policy concerns, found that it cost employers 15-17% more when they failed to provide contraception coverage.[18] And most recently, a 2016 study of the implications of the ACA contraceptive mandate found:

> … increased utilization achieved by making contraception available through employer-based insurance plans at no cost sharing for women of childbearing years may be a highly successful strategy in reducing unwanted and mistimed pregnancies, terminations and associated costs. From the perspective of the health plan, coverage of contraception reduces costs for all members. From the employer perspective, coverage of contraception may avoid additional expenses incurred due to unintended pregnancies among employees, such as economic losses associated with employee absenteeism, decreased productivity, higher employee replacement costs, maternity leave, sick leave and loss of employees due to pregnancy.[19]

Thus, requiring coverage of all FDA approved contraceptives without a co-payment strikes the right balance between reducing unintended pregnancies and allowing insurers to control cost.

Further, we recommend that the Department include coverage for male methods of contraception – both vasectomies and condoms with a prescription –to acknowledge the critical role men must play in the prevention of unintended pregnancy. Vasectomies are among the most effective and cost-effective contraceptive methods available and are less invasive and carry fewer risks than female sterilization.[20] Male condoms, since they provide protection against sexually transmitted infections as well, are often paired with another form of birth control – in

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[16] Testimony of Guttmacher Institute Submitted to the Committee on Preventive Services for Women Institute of Medicine (Jan. 12, 2011), https://www.guttmacher.org/sites/default/files/article_files/cpsw-testimony.pdf

[17] J.J. Frost, et al., *Contraceptive Needs and Services, National and State Data*, Guttmacher Institute (2010). *See also* J. Edwards, et al., *Evaluation of Medicaid Family Planning Demonstrations*, CNA Corp., Alexandria VA (2003).

[18] Rowena Bonoan & Julianna Gonen, *Promoting Health Pregnancies: Counseling and Contraception as the First Step*. Family Health in Brief no.3. Washington Business Group on Health, Washington D.C. (2000).

[19] Will Canestaro, et al., *Implications of Employer Coverage of Contraception: Cost-effectiveness Analysis of Contraception Coverage Under an Employer Mandate*. 95 Contraception International Reproductive Health Journal 77 (2017), http://dx.doi.org/10.1016/j.contraception.2016.08.002.

[20] Guttmacher Institute, *Contraceptive Use in the United States, In Brief* (2014), http://www.guttmacher.org/pubs/fb_contr_use.pdf. *See also* James Trussell, *Update On and Correction to the Cost-effectiveness of Contraceptives in the United States*. 85 Contraception International Reproductive Health Journal 611 (2012).

fact, 15% of female contraception users rely on male condoms.[21] Limiting insurance coverage of contraception to female methods creates a financial incentive for heterosexual couples to put the onus of contraception on the woman and reinforces the cultural attitude that contraception is a woman's responsibility.[22] Furthermore, limiting contraceptive coverage is inconsistent with coverage of contraception through Medicaid and Title X programs, which have consistently provided equal coverage for male and female contraception.[23]

By requiring broader contraceptive coverage for all federal FDA approved types of contraception within the 18 categories without a co-payment, the proposed rule would lead to more timely access and thus reduce the likelihood of unintended pregnancy. For this reason, we strongly recommend broadening the category of contraceptives that are covered without a co-payment to reflect the standard within New York's Women's Health and Wellness Act.

2. The Department should remove the limitations on accessing a 12-month supply of birth control.

The proposed rule requires insurers to cover the dispensing of an initial three-month supply of a contraceptive to an insured; and for subsequent dispensing of the same contraceptive prescribed by the same health care provider and covered under the same policy, to cover the dispensing of the entire prescribed supply up to 12 months. The laudable aim of this policy is to align with the recent recommendations by the Centers for Disease Control and Prevention, which state that providers can enable consistent use of contraception when they "provide or prescribe multiple cycles (ideally a full year's supply) of oral contraceptives, the patch, or the ring."[24] Uninterrupted use is critical to improving contraceptive efficacy and reducing the rate of unintended pregnancy and studies show that dispensing a one-year supply of contraceptives, as opposed to a three- or one-month supply, is associated with a 30% reduction in the likelihood of an unplanned pregnancy, as well as cost savings to private insurers and the state.[25] Unfortunately, the proposed rule contains unnecessary barriers to accessing the 12-month supply that will hamper the effectiveness of the rule.

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[21] Kimberly Daniels, et al., *Current Contraceptive Status Among Women Aged 15–44: United States, 2011–2013*. NCHS Data Brief No. 173 (2014), http://www.cdc.gov/nchs/data/databriefs/db173.pdf.

[22] Adam Sonfield, *Rounding Out the Contraceptive Coverage Guarantee: Why 'Male' Contraceptive Methods Matter for Everyone*,18 Guttmacher Policy Review 34 (2015), https://www.guttmacher.org/gpr/2015/06/rounding-out-contraceptive-coverage-guarantee-why-male-contraceptive-methods-matter.

[23] *Id.*

[24] Loretta Gavin, et al., *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs Recommendations and Reports*, U.S. Centers for Disease Control and Prevention (2014), http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm.

[25] Diana Greene Foster, et al., *Number of Oral Contraceptive Pill Packages Dispensed and Subsequent Unintended*, 711 Obstetrics & Gynecology 566 (2011). *See also* Committee on Health Care for Underserved Women, The American College of Obstetricians and Gynecologists, *Committee Opinion: Access to Contraception*, no. 615 (2015) (supporting the provision of one year of contraception to reduce cost and improve adherence and continuation rates, and noting that "[i]nsurance plan restrictions prevent 73% of women from receiving more than a single month's supply of contraception at a time").

First, the rule requires an initial three-month supply be distributed to the insured before the patient can access a 12-month supply. Although decisions about what birth control is right for an individual woman are complicated and may take time and experimentation, they are best left to the woman and her medical provider and should not be driven by the intricacies of insurance coverage. Women, on average, spend three decades of their lives trying to avoid an unintended pregnancy. This means that patients may use the same contraceptive method for long spans of time. Simply requiring coverage for a 12-month supply does not stop a medical provider from prescribing a smaller amount if there is a medical reason to do so, and there is no reason to impose an initial three-month dispersal limitation on a woman if she and her doctor have decided that this is the right birth control for her.

Second, the proposed rule requires that the same health care provider prescribe the subsequently prescribed 12-month supply. Many women are unable to have a consistent relationship with one medical provider, especially those who have limited access to health care points of services or those who experience frequent changes in their insurance coverage status. There is no medical reason that a prescription for the same medication from a different provider would have a different effect or need a smaller number of months dispensed where the goal is to reduce unintended pregnancies and in a health care system that is attempting to stress seamless delivery of care. Requiring that the same health care provider prescribe the contraception to access a 12-month supply is an unfair burden that will fall hardest on those who are low income and in rural communities.

For these reasons, the Sex and Law Committee recommends simply requiring coverage for a 12-month dispensing of contraception at one time. If the barrier of an initial 3-month supply is kept in place, we would urge removing the requirement that the latter supply be prescribed by the same health care provider. Decisions on the medically appropriate amount of medication is best left to a medical provider, not an insurance company, and creating unnecessary barriers to a 12-month supply will only result in undermining the stated purpose of the proposed rule, i.e., to reduce unintended pregnancies.

Contraception is a critical component of basic care for women. Women need meaningful access to contraception to plan their lives and protect their health. The Sex and Law Committee applauds the Department for working to reduce barriers to contraception. The proposed rule should be further strengthened in accordance with the recommendations above.

Sex and Law Committee
Katharine Bodde, Chair

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