



# **Model Contraceptive Equity Act:** Legislative Language and Issue Brief

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# Executive Summary

Contraceptive Equity is a policy framework under which contraceptive care is easily accessible and covered at no cost in all health plans. Why is it important? Because of the critical role that family planning plays in improving health outcomes and economic security, and because of the historically inadequate coverage of comprehensive birth control services. While many states have Contraceptive **Parity** laws, requiring coverage of contraceptives in the same manner as other prescription drugs, and the Affordable Care Act (ACA) creates federal requirements for contraceptive **coverage**, Contraceptive **Equity** remains elusive.

Contraceptive Equity laws, which started to be introduced in states in 2014, go beyond existing standards and prevent insurers from using medical management techniques, like cost-sharing, prior authorization, prescription requirements, gender restrictions, or quantity limitations, to erect access barriers. In the wake of the first Contraceptive Equity law in California, co-sponsored by the National Health Law Program (NHeLP) and Essential Access Health, NHeLP created a Model Contraceptive Equity Act (Model Act). The Model Act has been used to introduce similar legislation in 40 jurisdictions and enact versions in 15 states and Washington, D.C.

This paper will begin with the Model Act legislative language that can serve as a template for state advocates. Recently added for 2023, the Model Act now includes:

- New findings related to the COVID-19 public health emergency;
- Language making it easier to get a 12-month supply of contraception;
- A range of enforcement mechanisms, including regulations, stakeholder meetings, market conduct reviews, and legislative reports; and
- Definitions that explicitly regulate pharmacy benefit managers.

The paper concludes with an issue brief explaining the provisions within the Model Act and how Contraceptive Equity takes major steps toward equitable access to contraceptive services for people of all genders. By enacting these laws, states are ensuring that coverage of contraceptives will survive regardless of what happens to federal requirements embedded in the ACA. These laws will be crucial to maintain and expand access to reproductive health care moving forward.

***NHeLP is available to provide technical support to advocates who are considering a Contraceptive Equity Act in their state. For more information, please contact Liz McCaman Taylor at [mccaman@healthlaw.org](mailto:mccaman@healthlaw.org).***

# Legislative Language:

## The Contraceptive Equity Act of 2023

*\*NOTE: State-specific terms and optional provisions are in [brackets].*

### SECTION 1.

The Legislature hereby finds and declares all of the following:

- (a) [name of state] has a long history of expanding timely access to birth control to prevent unintended pregnancy.
- (b) Medical management techniques such as denials, step therapy, or prior authorization in public and private health care coverage can impede access to the most effective contraceptive methods.
- (c) Many insurance companies do not typically cover male methods of contraception or they require high cost-sharing despite the critical role people of all genders play in the prevention of unintended pregnancy.
- (d) The COVID-19 public health emergency has further illuminated the structural inequities that disproportionately affect youth, low-income people, and communities of color in accessing birth control services. A report by the Guttmacher Institute revealed that 29 percent of white women, 38 percent of Black women, and 45 percent of Latinas now face difficulties accessing birth control as a result of the pandemic.<sup>1</sup>
- (e) Sexually transmitted infections, already at record highs, have continued to increase during the COVID-19 public health emergency. Condoms are the only current contraceptive method that prevent both pregnancy and sexually transmitted infections.
- (f) The federal Patient Protection and Affordable Care Act includes a contraceptive coverage guarantee as part of a broader requirement for health insurance to cover key preventive care services without out-of-pocket costs for patients.
- (g) The Legislature intends to build on existing state and federal law to promote gender equity and sexual and reproductive health, and to ensure greater contraceptive coverage equity and timely access to all federal Food and Drug Administration (FDA) identified birth control drugs, devices, and products, and related services, for all individuals covered by [health care service plan contracts] in [name of state].
- (h) The Legislature intends for the relevant [state] departments and agencies to work in concert to ensure compliance with these provisions.

<sup>1</sup> See Laura D. Lindberg, et. al, *Early Impacts of the COVID-19 Pandemic: Findings from the 2020 Guttmacher Survey of Reproductive Health Experiences*, GUTTMACHER INSTITUTE (June 2020), <https://www.guttmacher.org/report/early-impacts-covid-19-pandemic-findings-2020-guttmacher-survey-reproductive-health>.

## SECTION 2.

(a) Requirements for a [Health Care Service Plan].

(1) A [health care service plan] contract, except for a [specialized health care service plan contract], that is issued, amended, renewed, effective or delivered [on or after January 1, 2024], shall provide coverage for all of the following:

(A) All FDA-approved contraceptive drugs, devices, and other products, including those prescribed by the covered person's provider or as otherwise authorized under state or federal law, and all FDA-approved over-the-counter contraceptive drugs, devices, and products, subject to the following:

- (i) If the FDA has approved one or more therapeutic equivalents, as that term is defined by the FDA, of a prescription contraceptive drug, device, or product, the [health care service plan] must include either the original FDA-approved prescription contraceptive drug, device, or product or at least one of its therapeutic equivalents. If there is no therapeutic equivalent, the [health care service plan] must include the original, brand name contraceptive.
- (ii) If the covered contraceptive drug, device, or product is not tolerated or is inappropriate for a patient as determined by the patient and the provider, the [health care service plan] shall defer to the determination and judgment of the attending provider and provide coverage for the alternate prescribed contraceptive drug, device, or product.
- (iii) This coverage must provide for the single dispensing of [prescription] contraceptives intended to last the patient for a 12-month duration, which may be furnished or dispensed all at once or over the course of the 12 months at the discretion of the prescriber. The [health care service plan] shall reimburse a health care provider or dispensing entity per unit for furnishing or dispensing an extended supply of [prescription] contraceptives.

(B) Voluntary sterilization procedures;

(C) Clinical services related to the provision or use of contraception, including consultations, examinations, procedures, device insertion, ultrasound, anesthesia, patient education, referrals, and counseling; and

(D) Follow-up services related to the drugs, devices, products, and procedures covered under this subdivision, including, but not limited to, management of side effects, counseling for continued adherence, and device removal.

- (2) A [health care service plan] subject to this section:
- (A) Shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this section, unless the health plan is offered as a qualifying high-deductible health plan for a health savings account. For such a qualifying high-deductible health plan, the carrier shall establish the plan's cost-sharing for the coverage provided pursuant to this section at the minimum level necessary to preserve the enrollee's ability to claim tax-exempt contributions and withdrawals from their health savings account under Internal Revenue Service laws, regulations, and guidance;
  - (B) Shall not require a prescription to trigger coverage of FDA approved over-the-counter contraceptive drugs, devices, and products, and shall provide point-of-sale coverage for over-the-counter contraceptives at in-network pharmacies without cost-sharing or medical management restrictions; and
  - (C) Shall not impose utilization control or other forms of medical management limiting the supply of FDA-approved [prescription] contraception that may be dispensed or furnished by a provider or pharmacist, or at a location licensed or otherwise authorized to dispense drugs or supplies to an amount that is less than a 12-month supply, and shall not require an enrollee to make any formal request for such coverage other than a pharmacy claim.
  - (D) [This subsection does not apply to grandfathered health plans.]
- (3) Except as otherwise authorized under this section, a [health care service plan] shall not impose any restrictions or delays on the coverage required under this section.
- (4) Benefits for an enrollee under this section shall be the same for an enrollee's covered spouse [or domestic partner] and covered non-spouse dependents.
- (5) If needed, the [relevant state agency] shall submit a State Plan Amendment in accordance with the federal Social Security Act in order to implement this section.
- (b) Religious Employers. A religious employer may request a [health care service plan] contract without coverage for FDA-approved contraceptive methods used for contraceptive purposes that are contrary to the religious employer's religious tenets. If so requested, a [health care service plan] shall be provided without coverage for requested contraceptives. The exclusion from coverage under this provision shall not apply to contraceptive services or procedures provided for purposes other than contraception, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause.

- (1) A [health care service plan] that contracts with a religious employer to provide a [health care service plan] that does not include coverage and benefits for FDA-approved contraceptive methods used for contraceptive purposes shall notify, in writing, upon initial enrollment and annually thereafter upon renewal, each enrollee that FDA-approved contraceptive methods used for contraceptive purposes are not included in the enrollee's [health care service plan], and of existing programs in [state], including but not limited to [state Medicaid family planning program], which offer no- or low-cost contraceptive care.
- (c) Nothing in this section shall be construed to exclude coverage for contraceptive supplies as prescribed by a provider, acting within their scope of practice, for reasons other than contraceptive purposes, such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an enrollee.
- (d) The [department] must monitor [health care service plan] compliance in accordance with [relevant statute], and (may/shall) adopt rules for the implementation of this section, including the following:
- (1) In addition to any requirements under state administrative procedures, the [department] must engage in a stakeholder process prior to the adoption of rules that includes [health care service plans], pharmacy benefit plans, consumer representatives, including those representing youth, low-income people, and communities of color, and other interested parties. The [department] shall hold stakeholder meetings for stakeholders of different types to ensure sufficient opportunity to consider factors and processes relevant to contraceptive coverage. The [department] shall provide notice of stakeholder meetings on the [division] website, and stakeholder meetings shall be open to the public.
  - (2) The [department] (may/shall) conduct random reviews of each [health care service plan] and its subcontractors to ensure compliance with this section.
  - (3) The [department] shall submit an annual report to the Legislature and any other appropriate entity with its findings from the random compliance reviews detailed in subsection (d)(2) above and any other compliance or implementation efforts. This report shall be made available to the public on the [department]'s website.
  - (4) Nothing in this section shall be construed to deny or restrict in any way [the department's] authority to ensure compliance with [insert cite to any relevant state law] when a [health care service plan] provides coverage for contraceptive drugs, devices, and products.

(e) A [health care service plan] that violates this section is subject to sanctions, in accordance with [relevant statute]. The [department] may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.<sup>2</sup>

(f) Nothing in this section shall be construed to require a [health care service plan] contract to cover experimental or investigational treatments.

(g) Definitions. For purposes of this section, the following definitions apply:

- (1) “Grandfathered health plan” has the meaning set forth in Section 1251 of the federal Patient Protection and Affordable Care Act (Public Law 111-148), as amended by the federal Health Care and Education Reconciliation Act of 2010 (Public Law 111-152), and any rules, regulations, or guidance issued thereunder.
- (2) “[Health care service plan]” has the meaning set forth in [relevant state law] and shall include all pharmacy benefit managers and Medicaid [and CHIP] managed care plans that contract with the State [insert single state agency and relevant referencing statutes].
- (3) “Provider” means an individual who is certified or licensed pursuant to [insert state licensing provisions referencing any medical professional with prescriptive authority including medical professionals, pharmacists, emergency medical personnel, etc. under state law].
- (4) A “religious employer” is an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.
- (5) A [“specialized health care service plan”] is a plan that does not provide comprehensive services such as a dental-only plan or a vision-only plan.
- (6) A “therapeutic equivalent” has the meaning set forth by the Food and Drug Administration.

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<sup>2</sup> Note, if no relevant state law exists, this statute or accompanying regulations will need to explicitly delineate sanction type and degree. See, e.g., 42 CFR §§ 460.40–.56.

# Issue Brief: An Overview of the Provisions in the Model Act

The Affordable Care Act (ACA) added § 2713 to the Public Health Service Act (PHSA), which requires coverage of certain women’s health preventive services without cost-sharing as described in guidelines promulgated by the Health Resources and Services Administration (HRSA).<sup>3</sup> HRSA guidelines require coverage of “[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity.”<sup>4</sup>

While this requirement is a welcome and significant step forward, exceptions, as well as insufficient specificity in the federal law have led to inadequate and inconsistent implementation. For example, federal regulations permit carriers to employ “reasonable medical management techniques,” which are insurer-imposed limitations. The federal guidance does not define the term or its parameters. Medical management is rarely appropriate in contraceptive care.

The federal law also fails to recognize the important role that men play in preventing unintended pregnancy. For example, the ACA’s coverage requirement does not extend to men or include male methods of contraception. In addition, the federal law allows issuers to impose a prescription requirement on FDA-approved methods that are available over-the-counter (OTC). While women are still entitled to coverage of these methods without cost-sharing, the need to see a provider and obtain a prescription is a medically unnecessary barrier that undermines the accessibility granted by OTC status.

The Model Contraceptive Equity Act (Model Act) seeks to improve access to all FDA-approved methods of contraception for all individuals by building on current state and federal law to:

1. Require insurance coverage of all FDA-approved contraceptive drugs, devices, and other products; voluntary sterilization; comprehensive contraceptive counseling; and other related services including device insertion and removal;
2. Strictly limit the ability of insurers to impose restrictions and delays (referred to as medical management or utilization controls);
3. Require coverage of OTC contraceptives without a prescription; and

<sup>3</sup> 42 U.S.C. § 300gg-13(a)(4).

<sup>4</sup> The complete Guidelines for Women’s Preventive Services can be found on the HRSA website at <https://www.hrsa.gov/womens-guidelines>.

4. Create equity in the contraceptive coverage mandate by eliminating cost-sharing for contraception, voluntary sterilization, and contraceptive counseling for men.

This issue brief provides an overview of the provisions in the Model Act meant to achieve these four primary goals.

## I. OVERVIEW OF THE MODEL ACT

### 1. Require insurance coverage of all FDA-approved contraceptive drugs, devices, and other products, voluntary sterilization, comprehensive contraceptive counseling, and other related services

#### All Means All

The U.S. Departments of Health and Human Services, Labor, and Treasury (the Departments) clarified in May 2015 that the ACA requirement to cover “all FDA-approved contraceptive methods” for women means that plans must provide coverage without cost-sharing for at least one form of contraception in each of the 17 FDA-approved contraceptive method categories. This requirement is not explicitly enshrined in regulation or law.<sup>5</sup> In addition, without appropriate enforcement we can expect continued reports of insurers around the country failing to cover particular contraceptives based on a flawed definition of what constitutes a contraceptive “method,” and what it means to cover “all methods.” For example, a review of plan documents prior to the May 2015 guidance from the Departments by the Guttmacher Institute found that multiple insurers “appear to be excluding the contraceptive ring and patch from coverage at no cost-sharing, apparently under the theory that because they use the same hormonal ingredient used in certain oral contraceptives, they do not qualify as distinct methods.”<sup>6</sup> This is contrary to the FDA’s *Birth Control Guide*, which clearly lists seventeen distinct method categories for women and two for men.<sup>7</sup> Moreover, the May 2015 FAQ would still allow a plan to cover only one progestin IUD (either Mirena, Skyla, Liletta, or Kyleena), as they all fall into the same category, even though they are distinct contraceptives. All must be covered under the Model Act.

<sup>5</sup> U.S. Dep’t of Labor, Health & Human Serv., & Treasury, *Frequently Asked Questions about Affordable Care Act Implementation Part XXVI* (May 11, 2015), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> [hereinafter *May 2015 FAQ*].

<sup>6</sup> Adam Sonfield, Implementing the Federal Contraceptive Coverage Guarantee: Progress and Prospects, *GUTTMACHER POL’Y REV.*, Fall 2013, at 8, <http://www.guttmacher.org/pubs/gpr/16/4/gpr160408.html>.

<sup>7</sup> U.S. Food & Drug Admin., *Birth Control Guide*, <https://www.fda.gov/media/135111/download>.

The Model Act uses the phrase “all FDA-approved contraceptive drugs, devices, and other products” instead of “all FDA-approved contraceptive methods” or “the full range of FDA-approved contraceptive methods.” Under this language, insurers would be required to cover all FDA-approved contraceptive products, except as provided in subsection (a)(1)(A)(i), explained below.

The Model Act does not require coverage of every original and generic contraceptive. It strikes the balance between allowing insurers to continue to control costs by utilizing formularies and ensuring that individuals can obtain the contraceptive that is best for them. Subsection (a)(1)(A)(i) of the Model Act allows an exception for FDA-designated, therapeutically equivalent prescription contraceptive drug products. In other words, when the FDA has classified drugs as “therapeutic equivalents,” a plan is only required to cover one of the therapeutic equivalents as they can be substituted for one another with the full expectation that they will produce the same clinical effect and safety profile. However, some drugs, devices, and products approved by the FDA are unique and do not have a therapeutic equivalent, in which case the original must be covered without cost-sharing.

Therapeutically equivalent drug products contain the same active ingredient(s), dosage form and route of administration, and strength.<sup>8</sup> This framework prevents a plan from refusing to cover a range of methods that have the same hormonal content but different dosage forms or routes of administration. This addresses the insurance practice of only covering one IUD, or refusing to cover the ring because it has the same hormonal content as an oral contraceptive pill.

The FDA considers drug products to be therapeutic equivalents if they meet the criteria outlined above, even though they may differ in other characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration date/time and minor aspects of labeling and storage conditions.<sup>9</sup>

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<sup>8</sup> *Id.* The “dosage form and route of administration” is the delivery mechanism of the contraceptive, such as a pill, a patch, a ring, an intrauterine device, or an implant.<sup>8</sup> A comprehensive list of specific dosage forms is online at <https://www.fda.gov/forindustry/datastandards/structuredproductlabeling/ucm162038.htm>. To be considered therapeutic equivalents, drug products must be *bioequivalent*, meaning they do not present a known or potential bioequivalence problem and meet an acceptable *in vitro* standard, or have been shown to meet an appropriate bioequivalence standard.<sup>8</sup> See U.S. Food & Drug Admin., *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)* vii (37<sup>th</sup> Ed. 2016), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf>.

<sup>9</sup> U.S. Food & Drug Admin., *Approved Drug Products*, *supra* note 10, at vii.

Many oral contraceptives have multiple FDA-approved therapeutically equivalent versions currently on the market. For example, Cyclessa, Kariva, Pimtreea, and Viorele are all classified as therapeutic equivalents.<sup>10</sup> Subsection (a)(1)(A)(i) would allow plans to cover only one of these drugs without cost-sharing, thus allowing a formulary design that either leaves the other versions off the formulary completely or places them in higher tiers where cost-sharing or utilization controls are permissible. At the same time, a plan would still have to cover all other therapeutically distinct oral contraceptive pills (i.e. those with different strengths and hormonal formulations), as well as off-formulary or higher tiered contraceptives deemed medically required by the provider, without cost-sharing.

Drug products such as NuvaRing, Skyla, ParaGard, Mirena, Kyleena, and Liletta do not have any FDA-designated therapeutic equivalents; therefore, plans would be required to cover each of them in accordance with the Model Act.

Notably, OTC drug products are not assigned therapeutic equivalence codes. For this reason, subsection (a)(1)(A)(i) applies only to prescription contraceptive drug products. Some retail pharmacies may stock a limited selection of OTC contraceptives – in particular emergency contraception, and therefore the Model Act does not give insurers flexibility to limit OTC coverage. This is an important consumer protection and could prevent any delays in access, which is critical in the case of OTC emergency contraception.

As noted above, rare circumstances may exist when even the small differences between therapeutically equivalent drugs may be important to a particular patient. The FDA recognizes, “when such differences are important in the care of a particular patient, it may be appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity.”<sup>11</sup> Therefore, subsection (a)(1)(A)(ii) provides a mechanism for enrollees to access a non-covered or higher tiered contraceptive with no cost-sharing when a covered product is not tolerated or deemed inappropriate for a patient, as determined by the patient and the provider. This is a lower bar than medical necessity, allowing provider discretion to be weightier and less subject to review than it might be under a strict medical necessity standard.

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<sup>10</sup> A database of FDA-approved drugs and their therapeutic equivalents is online at <https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

<sup>11</sup> *Id.*

## Services Related to Contraception

The Model Act also requires coverage without cost-sharing of follow-up services related to the contraceptive drugs, devices, products, and procedures covered under the Act. These specifically include, but are not limited to, management of side effects, counseling for continued adherence, and device insertion and removal. This language is nearly identical to the federal requirement found in Q16 of *FAQs About Affordable Care Act Implementation Part XII*.<sup>12</sup> However, the Model Act also explicitly includes device insertion, which is implicit in the federal requirements but not clearly stated.

### **2. Medical Management: Strictly limit the ability of insurers to impose restrictions and delays**

One of the primary goals of the Model Act is to eliminate delays in access or restrictions on particular contraceptive methods by strictly limiting medical management for contraception.<sup>13</sup> Medical management techniques are insurer-imposed conditions under which a person can obtain a drug or service. They include step-therapy – where a patient has to try one method and “fail” (which could include pregnancy or medical complications) before the insurer will authorize what may be a more expensive method – or prior authorization by the insurer. For example, one insurer in California required enrollees to take oral contraceptives for three months and “fail” before they would authorize the contraceptive patch. Prior authorization may require a woman to make a second office visit to get her method of choice. Techniques that effectively deny or delay a woman’s access to her preferred method not only limit reproductive autonomy, they also may lead to lapsed or inconsistent contraceptive use and increased risk of unintended pregnancy.

The Model Act provides a near prohibition on medical management in the context of contraceptive coverage. It also includes a legislative finding specifically addressing medical management: “(d) Medical management techniques such as denials, step therapy, or prior authorization in public and private health care coverage can impede access to the most effective contraceptive methods.”

<sup>12</sup> U.S. Dep’t of Labor, Health & Human Serv., & Treasury, *Frequently Asked Questions about Affordable Care Act Implementation Part XII* Q16 (February 20, 2013), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf>.

<sup>13</sup> For a fuller discussion of medical management and contraception, see Erin Armstrong and Agata Pelka, National Health Law Program, *Medical Management and Access to Contraception* (2016), <https://healthlaw.org/resource/medical-management-and-access-to-contraception/>.

The two exceptions authorized under the Model Act are: 1) OTC “as prescribed” language (discussed in the next section); and, 2) the flexibility in subsection (a)(1)(A)(i) to allow coverage of only one in a group of multiple therapeutically equivalent prescription drugs (discussed above).

### **3. Require coverage of over-the-counter contraceptives without a prescription**

The Model Act clarifies that contraceptive coverage includes “all FDA-approved over-the-counter contraceptive drugs, devices, and products” and does “not require a prescription to trigger coverage of over-the-counter contraceptive[s].”

The Model Act includes the phrase “or as otherwise authorized under state or federal law.” This language is intended to avoid the need for an amendment in the event that ongoing efforts to remove prescription requirements at both the state and federal levels are successful. This language is particularly important in states that already permit Medicaid coverage of OTC drugs without a prescription to the extent this piece of the Model Act would apply to Medicaid in those states, because it eliminates the delays that can be caused by a prescription requirement.

### **4. Create equity in the contraceptive coverage mandate by eliminating cost-sharing for contraception, voluntary sterilization, and contraceptive counseling for men**

As mentioned above, the ACA’s coverage requirement does not extend to men or include male methods of contraception. This exclusion allows carriers to deny coverage of vasectomy services and male condoms, forcing men to continue paying out of pocket if they choose to share in the responsibility for preventing an unintended pregnancy. According to an article in *Contraception Journal*, many insurance carriers do not cover vasectomy at all; and because the cost of a vasectomy is so high, even when insurers provide coverage for the procedure, the remaining co-pay may still be significant.<sup>14</sup> To address this shortcoming in the federal law, the Model Act uses gender-neutral language throughout and includes a finding specific to men.<sup>15</sup>

<sup>14</sup> Brian T. Nguyen et al., “Putting the Man in Contraceptive Mandate,” *CONTRACEPTION: INT’L REPROD. HEALTH J.*, Jan. 2014, [https://www.contraceptionjournal.org/article/S0010-7824\(13\)00641-0/references](https://www.contraceptionjournal.org/article/S0010-7824(13)00641-0/references).

<sup>15</sup> Note that in some states it may be prudent to remain gender neutral but to divide the Model Act into two statutes: one mandating coverage of traditionally women’s services and another eliminating cost-sharing for traditionally men’s services. The rationale behind this division is explained in more detail below under Essential Health Benefits, State Mandates, and Gender Equity. For examples of Model Act language with this division, please contact NHeLP.

To date, eight states have included vasectomy coverage requirements without cost-sharing in their enacted state legislation. However, recent sub-regulatory guidance from the Internal Revenue Service (IRS) has compelled these states to consider how these coverage requirements apply to high-deductible health plans (HDHPs). Normally, a consumer with an HDHP in conjunction with a tax-exempt Health Savings Account (HSA), must meet the deductible before receiving any benefits. Federal law explicitly provides an exemption or “safe harbor” to allow HDHPs to cover preventive services before a patient meets the minimum deductible requirements.<sup>16</sup> IRS guidance from 2013 clarified that all of the FDA-approved contraceptive methods for women, including women’s sterilization, are considered preventive services for tax purposes.<sup>17</sup> However, in March 2018, the IRS issued additional guidance stating that because the Affordable Care Act did not include a men’s preventive services amendment, male sterilization, male condoms, and related services are not considered preventive in the context of HSAs.<sup>18</sup> This conclusion is unfortunate given the public health argument for classifying all contraception as preventive, and since male contraception benefits both women and men.<sup>19</sup>

Given this directive, the Model Act fully covers male condoms and vasectomies without cost-sharing in HDHPs once the consumer’s annual deductible requirements are met. This language, found in section 2(a)(2)(A) of the Model Act, complies with existing IRS guidance, but does not foreclose the ability of the no cost-sharing provision to kick-in for HDHPs in the case that a future administration makes a determination that vasectomy is a preventive service. In addition, if the US Preventive Services Task Force (USPSTF)

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<sup>16</sup> 26 USC § 223(c)(2).

<sup>17</sup> Internal Revenue Service, *Preventive Health Services Required Under Public Health Service Act Section 2713 and Preventive Care for Purposes of Health Savings Accounts* (Sep. 9, 2013), <https://www.irs.gov/pub/irs-drop/n-13-57.pdf>.

<sup>18</sup> Internal Revenue Service, *Notice of Transition Relief Regarding the Application of Section 223 to Certain Health Plans Providing Benefits for Male Sterilization or Male Contraceptives* (Mar. 5, 2018), <https://www.irs.gov/pub/irs-drop/n-18-12.pdf>.

<sup>19</sup> See Adam Sonfield, “Rounding Out the Contraceptive Coverage Guarantee: Why ‘Male’ Contraceptive Methods Matter for Everyone,” 18 GUTTMACHER POL’Y REV. 34 (2015), <https://www.guttmacher.org/gpr/2015/06/rounding-out-contraceptive-coverage-guarantee-why-male-contraceptive-methods-matter>; *Condom Use: How It Relates to HIV and STI Prevention*, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (Sept. 2013), <https://www.usaid.gov/sites/default/files/documents/1864/CondomSTIIssueBrief.pdf>; J Trussell, et al., “The Economic Value of Contraception: A Comparison of 15 Methods,” 85 AM. J. PUB. HEALTH 494 (1995), <https://www.ncbi.nlm.nih.gov/pubmed/7702112/>; Andrew S. Ferber, et al., “Men with Vasectomies: A Study of Medical, Sexual, and Psychosocial Changes,” 29 PSYCHOSOMATIC MED. 354, 359-62 (1967).

issues an A or B rating for male contraception, coverage would be mandated as the ACA requires coverage without cost-sharing of USPSTF A and B recommendations.<sup>20</sup>

## II. ADDITIONAL ISSUES, QUESTIONS, AND CONCERNS

### 1. Essential Health Benefits, State Mandates, and Gender Equity

The ACA requires non-grandfathered health insurance coverage offered in the individual and small group markets (*i.e.*, fully-insured individual and small group coverage, including Qualified Health Plans, but not fully-insured large group coverage or self-insured group health plans) to cover the Essential Health Benefits (EHB) package for plan and policy years beginning on and after January 1, 2014. The EHB package must include ten specified categories of benefits.<sup>21</sup> To further define the scope of services covered in each of the ten categories, each state is required to select a “benchmark” plan from among a group of existing insurance plans identified by HHS.<sup>22</sup> The benchmark plan then serves as a reference plan for the purposes of identifying the specific services (and limitations) to be covered as part of the EHB package.

If a state enacts new benefit mandates after December 31, 2011 in addition to the EHB, federal law requires the state to defray the cost of those additional benefits through payments to enrollees or plan issuers. (Note that the state’s required payment for additional mandated benefits only applies to subsidized individuals enrolled in Qualified Health Plans – plans bought and sold in the state and federal insurance Marketplaces created by the ACA.) For this reason, some states may be reluctant to pass any new benefit mandates that fall outside of the EHB. Nevertheless, contraception is documented to ultimately save money and the state cost may be low.

Federal regulations separately require the EHB to include coverage of all preventive services required under the ACA, including all FDA-approved contraceptive methods for women.<sup>23</sup> Accordingly, the ACA’s contraceptive coverage requirement is already imbedded in the EHB. Importantly, this requirement is separate – and is not subject to – the rules and limitations regarding other prescription drugs in the EHB package. HHS has clarified that even if the EHB benchmark plan does not include the required

<sup>20</sup> 42 U.S.C. § 300gg-13(a)(1).

<sup>21</sup> 45 CFR § 156.110(a).

<sup>22</sup> 45 CFR § 156.100.

<sup>23</sup> 45 C.F.R. § 156.115(a)(3).

preventive services, all plans subject to the EHB requirements “must comply” with the ACA preventive services requirements.<sup>24</sup>

*The Model Act’s contraceptive coverage requirements for women are not a new mandate*

HHS has clarified that only new state mandates requiring that a health plan cover specific care, treatment, or services are considered for the purpose of evaluating whether state mandates are in excess of the EHB. The Model Act’s benefit (services) requirements for women are already incorporated in the EHB through federal regulations and therefore are not new. Rather, the Model Act addresses *how* those services are delivered and remedies insurance practices that have undermined access to those services.

From the preamble to a November 26, 2012 proposed federal rule:

In this proposed rule, we interpret state-required benefits to be specific to the care, treatment, and services that a state requires issuers to offer to its enrollees. Therefore, state rules related to provider types, cost-sharing, or reimbursement methods would not fall under our interpretation of state-required benefits. Even though plans must comply with those state requirements, there would be no federal obligation for states to defray the costs associated with those requirements.<sup>25</sup>

The same preamble also includes a specific illustration of how a state requirement pertaining to a delivery method does not trigger a requirement for the state to defray the cost:

For example, a state statute requiring issuers to pay the same for a physician consultation in the office and via telemedicine would not be a state-required benefit. The physician consultation is the service; the requirement to pay for telemedicine relates to payment for the service delivery method. Since the

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<sup>24</sup> See U.S. Dept. of Health & Human Svcs., Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans*, <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html> (last visited Dec. 6, 2021).

<sup>25</sup> 77 Fed. Reg 70644, 70647 (proposed Nov. 26, 2012).

requirement addresses a specific delivery method, not the underlying care, treatment, or service being delivered, there is no requirement to defray the cost.<sup>26</sup>

*The Model Act's requirements regarding contraceptive coverage for men may create a new state mandate*

The ACA contraceptive coverage requirements found in PHSA § 2713 do not include contraceptive services for men. Therefore, the EHB preventive services requirement does not include these services.

If contraceptive care for men, such as vasectomy, external condoms, and contraceptive counseling, are included in the state's EHB benchmark plan, the additional cost-sharing protection required under the Model Act does not constitute a new state mandate for purposes of the EHB and therefore does not trigger a requirement that the state defray the associated costs. As explained above in the excerpts from the November 2012 proposed rule, a cost-sharing mandate pertains to the way a service is paid for and does not address the underlying care, treatment, or service being delivered.

Nonetheless, because state agencies are responsible for reporting new mandates to the Centers for Medicare and Medicaid Services (CMS), advocates may consider a modification to the Model Act to further clarify that contraceptive care for men is not a new mandate. In California's SB 523, which NHeLP co-sponsored with Essential Access Health and NARAL Pro-Choice California, the coverage requirements were split across two statutes.<sup>27</sup> The statute mandating contraceptive coverage for traditionally women's services begins with a requirement that health plans "shall provide coverage" for contraception before moving on to the specific provisions prohibiting cost-sharing and medical management. Comparatively, the statute mandating contraceptive coverage for traditionally men's services that are included in the EHB eliminates the "shall provide coverage" language and moves directly into the cost-sharing and medical management prohibitions. This separation may assuage concerns around CMS oversight.

If contraceptive care for men is not included in the state's EHB benchmark plan at all, the additional cost-sharing protection required under the Model Act may constitute a new state mandate and trigger a requirement that the state defray the associated costs for Qualified Health Plans. To avoid being subject to defrayal, states could utilize the

<sup>26</sup> *Id.* This section of the proposed rule was finalized without change. 78 Fed. Reg. 12834, 12838 (Feb. 25, 2013).

<sup>27</sup> S.B. 523, 2021–22 Leg., Reg. Sess. (Ca. 2021), [https://leginfo.ca.gov/faces/billNavClient.xhtml?bill\\_id=202120220SB523](https://leginfo.ca.gov/faces/billNavClient.xhtml?bill_id=202120220SB523).

benchmarking process to expand or improve coverage. While this process takes longer than legislation or regulation requiring additional coverage (states must submit proposed changes 19 months in advance of their effective date and must submit actuarial certification that the resulting base-benchmark plan complies with typicality and generosity requirements), it is currently the only way to avoid having to defray the cost of new coverage mandates. States also have the option of creating targeted funds to cover the cost of the additional benefits during the months before the benchmarking changes become effective. The downside of this approach is that a future state administration could change the benchmark back or wind down the targeted program, which requires less oversight without an accompanying statutory mandate.

## 2. Application to Medicaid

The Model Act is written so that nearly all provisions apply to Medicaid managed care plans, in addition to other non-grandfathered individual and group health plans. This is important because Medicaid managed care organizations often apply medical management policies like step therapy and prior authorization to family planning. These utilization controls are less common, though still may exist, in Medicaid fee-for-service.

## 3. Religious Employers

The Model Act creates an exemption from the contraceptive coverage requirement for religious employers such as churches, which corresponds with HHS' 2014 definition of an exempt organization.

According to the Guttmacher Institute, 29 states have requirements that health insurance policies that cover prescription drugs must also cover prescription contraception (also known as “contraceptive parity” laws).<sup>28</sup> All but eight states allow some form of religious exemption (or refusal clause). Religious exemptions in state laws range from very narrow as in California and New York, to broadly exempting many religiously-affiliated non-profit organizations. Only Illinois allows an exemption for a secular entity. It is also important to note that these are full exemptions; none of the state laws include an accommodation similar to the federal rules that allow organizations to opt out of coverage, but still require that employees of those organizations are able to access contraceptive coverage.

The Supreme Court's decision in *Hobby Lobby*, which expanded the ACA's contraceptive coverage exemption to for-profit employers, was based on the federal

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<sup>28</sup> Guttmacher Institute, *State Policies in Brief: Insurance Coverage of Contraceptives* (as of Mar. 1, 2018), [http://www.guttmacher.org/statecenter/spibs/spib\\_ICC.pdf](http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf).

Religious Freedom Restoration Act (RFRA), which does not apply to state law.<sup>29</sup> A for-profit company or non-profit employer who might seek exemption – or accommodation – from the federal requirement, may still be bound by state law.

The Model Act does not allow exempted religious employers to refuse to cover contraceptives that are prescribed for a non-contraceptive purpose such as decreasing the risk of ovarian cancer or eliminating symptoms of menopause, or for contraception that is necessary to preserve the life or health of an enrollee.

#### 4. Preemption

Section 2724 of the PHSA, which addresses federal preemption of state laws applicable to plans and issuers, states (subject to certain limitations not relevant here):

[The provisions of the PHSA] shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.<sup>30</sup>

Accordingly, if a state law requiring coverage of one or more of the preventive services required to be covered by PHSA § 2713 is *more generous* to the individual than the federal coverage mandate (without being more restrictive in any way), then the state law likely would not be interpreted as “preventing the application” of the PHSA § 2713 preventive services coverage mandate. In this case, the state requirement would continue to apply to the issuer and plan, if applicable. If, on the other hand, a state law addressing coverage of one or more of the preventive services required to be covered by federal law is *less generous* to the individual than the federal coverage mandate, then compliance with just the provisions of the state statute likely would be viewed as preventing the application of the more generous federal law and thus preempted. For example, if an employer tried to claim an exemption from the federal mandate using a state’s RFRA, it would likely be preempted as applied to PHSA § 2713.<sup>31</sup>

Furthermore, the preamble to the final regulations implementing the contraceptive coverage requirement states explicitly that state laws that provide “greater access to

<sup>29</sup> See *City of Boerne v. Flores*, 521 U.S. 507 (1997).

<sup>30</sup> 42 U.S.C. § 300gg-23(a)(1).

<sup>31</sup> “State Religious Freedom Restoration Acts,” *National Conference of State Legislatures* (May 4, 2017), <http://www.ncsl.org/research/civil-and-criminal-justice/state-rfra-statutes.aspx>.

contraceptive coverage are unlikely to 'prevent the application of' the preventive services requirement, and are thus unlikely to be preempted by these final regulations."<sup>32</sup> The most recent interim final rules on religious and moral exemptions to the contraceptive coverage requirement also states that the:

[I]ndividual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.<sup>33</sup>

It further states that the interim final rules “do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirements in HRSA Guidelines supplied under section 2713 of the PHS Act.”<sup>34</sup>

Section 1321 of the ACA, implementing the Health Insurance Exchange (a.k.a. marketplace) provisions in Title I of the legislation, contains a similar provision protecting state laws that offer more generous benefits to individuals:

Nothing in [Title I of the ACA] shall be construed to preempt any State law that does not prevent the application of the provisions of this title.<sup>35</sup>

As described by the Departments in a 2010 Rule, “State laws that impose on health insurance issuers requirements that are stricter than those imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.”<sup>36</sup>

The Model Act provides for more generous benefits for the individual than required by the ACA, and it most likely would not be preempted.

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<sup>32</sup> Coverage of Certain Preventive Services under the Affordable Care Act, 78 Fed. Reg. 39870, 39888 (July 2, 2013).

<sup>33</sup> Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838, 47,853.

<sup>34</sup> *Id.* at 47,860.

<sup>35</sup> ACA § 1321(d). See e.g., *St. Louis Effort for Aids v. Huff*, No. 13-4246 (W.D. Mo. 2014) (providing an example of a state law that has been held to prevent application of the ACA).

<sup>36</sup> 75 Fed. Reg. 41726, 41727 (Jul. 19, 2010).

## Conclusion

State Contraceptive Equity acts have the potential to expand access to contraceptive coverage and ensure improved access to covered services without cost-sharing for women and men. NHeLP is available to provide technical support to state advocates who are considering a Contraceptive Equity Act in their state. If you would like more information, please contact Liz McCaman Taylor at [mccaman@healthlaw.org](mailto:mccaman@healthlaw.org).