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NATIONAL HEALTH LAW PROGRAM

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June 19, 2012

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-9968-ANPRM
P.O. Box 8016
Baltimore, MD 21244-1850

RE: CMS-9968-ANPRM
Certain Preventive Services Under the Affordable Care Act

Dear Sir/Madam:

The National Health Law Program ("NHeLP") is pleased to offer these comments on the Advanced Notice of Proposed Rulemaking for Certain Preventive Services Under the Affordable Care Act from the Department of the Treasury, Department of Labor, and Department of Health and Human Services ("ANPRM") published in the Federal Register on March 21, 2012.[1] NHeLP protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state levels. Consistent with this mission, NHeLP works to ensure that all people in the United States—including women—have access to preventive health services. The Patient Protection and Affordable Care Act ("ACA") similarly recognizes that preventive health services are critical to individual and community health, and that cost is often a barrier to accessing needed preventive services. By explicitly requiring that health insurance plans cover women's preventive health services without cost-sharing, the ACA further acknowledges both the critical role that a woman's health plays in the health and well-being of her family and her community, as well as her disproportionately lower earnings.[2]

NHeLP strongly supports the Department of Health and Human Services' ("HHS") requirement that most new health insurance plans cover women's preventive health services—including contraception—without cost-sharing.[3] HHS' decision is a significant triumph for millions of women who are currently insured or who will obtain health insurance through the

[1] Certain Preventive Services Under the Affordable Care Act, 77 Fed. Reg. 16,501 (Mar. 21, 2012) (to be codified at 45 C.F.R. pt. 147).
[2] Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010), § 1001, 42 U.S.C. § 300gg-13 (amending § 2713 of the Public Health Services Act ("PHS Act")).
[3] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., Women's Preventive Services: Required Health Plan Coverage Guidelines, http://www.hrsa.gov/womensguidelines.

ACA. Adherence to the HHS guidelines will ensure that most women have access to contraception without expensive co-pays, saving some women up to $600 per year. We are very concerned that the Department of the Treasury, Department of Labor, and HHS' ("Departments") ANPRM is considering "accommodations" for compliance with § 2713 of the Public Health Services Act ("PHS Act") for certain religiously-affiliated non-profit organizations.[4] Any such accommodation would create delays and erect barriers to contraceptive access. It will, moreover, not only undermine the intent of the ACA, but the health and autonomy of affected women as well. We therefore urge the Departments to reject this approach.

The Departments' healthcare coverage decisions should be based on accepted standards of medical care recognized by the various professional medical academies. This evidence-based approach is the framework on which the independent Institute of Medicine of the National Academies ("IOM") based its recommendations to HHS regarding the women's preventive health services that most health plans must cover without cost-sharing pursuant to § 2713 of the PHS Act.[5] The IOM's recommendations, which were adopted by HHS in its "Women's Preventive Services: Required Health Plan Coverage Guidelines," include coverage of all forms of Food and Drug Administration ("FDA")-approved contraceptive drugs and devices.[6] Guaranteeing women coverage of contraception is critical to protecting their health. A recent NHeLP report, *Health Care Refusals: Undermining Quality Care for Women*, a copy of which is attached to these comments, provides an extensive analysis of the adverse medical consequences for women when health care decisions are based on ideological beliefs instead of medical standards of care.[7]

The importance of a woman's ability to prevent pregnancy for many reasons is well established within medical guidelines across a range of practice areas. Women consider a number of factors in determining whether to become pregnant, including age, educational goals, economic situation, the presence of a partner and/or other children, medical condition, mental health, and whether they are taking medications that are contra-indicated for pregnancy. Further, millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. Denying these women access to contraceptive information and services does not comport with medical standards that recommend pregnancy prevention for these medical conditions. For example, according to the guidelines of the American Diabetes Association, planned pregnancies greatly facilitate diabetes care.[8] Their recommendations for women with diabetes of childbearing potential include (1) use of effective contraception at all

[4] 77 Fed. Reg. 16,501.
[5] Inst. of Medicine of the Nat'l Academies, *Clinical Preventive Services for Women: Closing the Gaps* (2011), www.iom.edu/~/media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/preventiveservicesforwomenreportbrief_updated2.pdf.
[6] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., *supra* note 3.
[7] National Health Law Program, *Health Care Refusals: Undermining Quality Care for Women* ("Standards of Care Report") (2010) (explaining that standards of care are defined as "practices that are medically necessary and the services that any practitioner under any circumstances should be expected to render"; "[s]tandards of care statements are created to indicate the level of clinical practice endorsed by scientists and clinicians and grounded in evidence from investigations of a particular area of practice").
[8] American Diabetes Ass'n, *Standards of Medical Care in Diabetes-2006*, 29 Diabetes Care S4, S28 (2006).

times, unless the patient is in good metabolic control and actively trying to conceive; (2) counseling about the risk of fetal impairment associated with unplanned pregnancies and poor metabolic control; and (3) maintenance of blood glucose levels as close to normal as possible for at least two to three months prior to conception.[9]

Notwithstanding the near universal agreement in medical practice guidelines that women should be given information about and access to contraceptives to prevent pregnancy, women face many barriers to contraceptive use, including cost. Unintended pregnancy rates are highest among low-income women, women aged 18-24, cohabiting women, and women of color.[10] Low-income women have higher rates of unintended pregnancy, as compared to higher-income women.[11] While low-income women are the least likely to have the resources to obtain reliable methods of family planning, they are the most likely to be impacted negatively by unintended pregnancy.[12] It is therefore not surprising that poor women's higher rate of unintended pregnancy results in their having higher rates of abortions and unplanned births.[13] Further, unintended pregnancy disproportionally impacts women of color: 67 percent of pregnancies among African American women, 53 percent of pregnancies among Latina women, and 40 percent of pregnancies among white women are unintended.[14]

RECOMMENDATION: Requiring coverage of all-FDA approved methods of contraception is critical to protecting women's health—it is also good medical and economic policy. Health care providers and religious employers who object to providing coverage for certain medical services based on their religious or moral beliefs are already protected by existing law. The Departments' ANPRM proposals are therefore unnecessary and unjustified. We oppose any efforts to further deprive women of contraceptive coverage.

If the Departments nevertheless proceed with the rulemaking process, we urge them to apply the following principles to their rulemaking:

1. **The religious employer exemption in regulations implementing § 2713 of the PHS Act establishes a delicate balance between protecting health care providers and meeting the health care needs of patients, and the Departments should not further broaden the exemption.**

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[9] *Id.*
[10] Lawrence B. Finer & Kathryn Kost, *Unintended Pregnancy Rates at the State Level*, Perspectives on Sexual & Reprod. Health Vol. 43, No. 2 (2011).
[11] Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001*, Perspectives on Sexual & Reprod. Health, Vol. 38, No. 2 (2006), http://www.guttmacher.org/pubs/psrh/full/3809006.pdf.
[12] Sheila D. Rustgi, Michelle M. Doty & Sara R. Collins, The Commonwealth Fund, *Women at Risk: Why Many Women are Forgoing Needed Health Care* (2009), http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf.
[13] Lawrence B. Finer & Mia R. Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, Contraception, Vol. 84, No. 5 (2011).
[14] *Id.*

We urge the Departments not to further expand the religious employer exemption codified in final regulations adopted on February 15, 2012.[15] The February 15, 2012 rule permits group health plans established or maintained by certain religious employers to refuse to provide coverage for contraceptive services, as they would otherwise be required under the law. [16] Notwithstanding HHS' decision to exempt certain religious employers from specified federal laws, there continues to be pressure to adopt ever more expansive refusal clauses. The ACA does not support broadening the religious-employer exemption. Doing so would only increase the number of low-income women and women of color who will likely go without care because of the out-of-pocket costs. A broader exemption would also perpetuate gender discrimination in health care, and threaten the health of millions of more women by making birth control financially inaccessible. An expanded exemption would undermine women's health and autonomy without furthering any constitutional right. The U.S. Constitution does not require the Departments to create an option to opt-out of the contraceptive coverage requirement.[17]

<u>RECOMMENDATION</u>: We urge the Departments to ensure—by declining to further broaden the religious employer exemption—that the IOM recommendations are properly implemented, and that women can make their own conscientious decisions about whether to use contraception that suits their particular health and life needs.

2. If the Departments proceed with an accommodation for non-exempted religious organizations, the accommodation should only apply to a nonprofit organization that is controlled or owned by an exempted religious organization.

We urge the Departments to require non-exempted religious organizations to provide contraceptive coverage to their employees or students. However, should the Departments decide to adopt an accommodation for certain non-exempted religious organizations, despite the adverse consequences on women's health and well-being, they should make the accommodation available only to nonprofit entities that are "owned or controlled" by a religious employer or organization that is exempt from HHS' "Women's Preventive Services: Required Health Plan Coverage Guidelines."[18] According to the final regulations implementing § 2713 of the PHS Act, an exempt religious employer is one that "(1) has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code."[19]

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[15] Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725 (Feb. 15, 2012) (to be codified at 45 C.F.R. pt. 147).
[16] *Id.*
[17] *See e.g.*, *Emp't Div., Dep't. of Human Res. of Or. v. Smith*, 494 U.S. 872, 879 (1990) *superseded by statute on other grounds*, 42 U.S.C. § 2000cc, *as recognized in* S*ossamon v. Texas*, 131 S. Ct. 1651, 1655-56 (2011).
[18] *See* U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., *supra* note 5; s*ee also e.g.*, HAW. REV. STAT. § 431:10A-116.7(a) ("For the purpose of this definition [of religious employer], any educational, health care, or other nonprofit institution or organization owned or controlled by the religious employer is included in this exemption.").
[19] Coverage of Certain Preventive Health Services, 45 C.F.R. § 147.130 (2012).

In addition, in order to qualify for an accommodation, the non-profit organization should meet additional criteria set forth below.

<u>RECOMMENDATION</u>: The Departments should require non-exempted organizations to provide contraceptive coverage to their employees and students. If the Departments, however, adopt an accommodation they should limit the definition of "religious organization" to nonprofit entities that are owned or controlled by a religious employer or organization exempt from HHS' "Women's Preventive Services: Required Health Plan Coverage Guidelines."[20]

a. Nonprofit organizations only.

The Departments should require that only nonprofit organizations can qualify for an accommodation to refuse to contract, arrange, or pay for contraceptive coverage. The purported goal of the accommodation is to protect an institution's exercise of religion while meeting the health care needs of women. In contrast, for-profit organizations exist to sell goods and services, and their objectives are commercial in nature. The Supreme Court has made clear that the Free Exercise Clause of the First Amendment to the U.S. Constitution is not offended when a for-profit enterprise is subject to a neutral law of general applicability.[21] The Court has further recognized,

> [w]hen followers of a particular sect enter into commercial activity as a matter of choice, the limits they accept on their own conduct as a matter of conscience and faith are not to be superimposed on the statutory schemes which are binding on others in that activity.[22]

The Constitution does not require the Departments to create any accommodation. Moreover, permitting a for-profit institution—whose primary purpose is unrelated to religious practice—to opt-out of complying with the law is particularly unjustified. The Departments should therefore exclude for-profit organizations from the definition of "religious organization." Further, if a nonprofit entity also has a for-profit division, or enters into a for-profit partnership or joint venture, the for-profit division or entity should be required to comply with § 2713 of the PHS Act (and not qualify for the accommodation). Finally, as with for-profit entities, the definition of "religious organization" should exclude health insurance issuers and third party administrators ("TPAs").

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[20] *See* U.S. Dep't of Health & Human Servs., *supra* note 5; *see also e.g.*, HAW. REV. STAT. § 431:10A-116.7(a) ("For the purpose of this definition [of religious employer], any educational, health care, or other nonprofit institution or organization owned or controlled by the religious employer is included in this exemption.").

[21] *See e.g.*, *Smith*, 494 U.S. at 879 (1990).

[22] *United States v. Lee*, 255 U.S. 252, 261 (1982), *abrogated by statute on other grounds*, 42 U.S.C. § 2000bb.

b. Nonprofit entities must be "owned or controlled" by exempted religious employers to qualify for the accommodation.

The Departments should identify specific criteria that determine if a nonprofit religious organization qualifies for an accommodation. We recommend that the Departments' definition of "religious organization" include only nonprofit religious organizations that are "owned or controlled" by an exempted organization. We recommend that the Departments use the following criteria to define "ownership":

(1) the organization shares common management and operations with the church, association of churches, or religious order;[23]
(2) the church, association of churches, or religious order controls the labor relations aspects of the organization;[24]
(3) the majority of the officers or board of directors are appointed by the church, association of churches, or religious order;[25] and
(4) the organization has a religious mission, as documented in its articles of incorporation or other governing documents, and the organization adheres to that religious mission.[26]

We recommend the follow criteria for "control":

(1) the majority of the officers or board of directors are appointed by the church, association of churches, or religious order;[27]
(2) the church, association of churches, or religious order has the authority to remove members of the organization's board;[28]
(3) the church, association of churches, or religious order is involved in the daily operation or strategic direction of the organization;[29]
(4) the organization has a religious mission, as documented in its articles of incorporation or other governing documents, and the organization adheres to that religious mission;[30]
(5) the organization receives significant financial support from the church, association of churches, or religious order;[31]
(6) the organization holds itself out to the public as sectarian;[32] and
(7) the organization regularly includes prayer, religious practices or traditions, or other forms of worship in its activities.[33]

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[23] *See e.g., Woodell v. United Way of Duchess Cnty*., 357 F. Supp. 2d 761, 767 (S.D.N.Y. 2005); *LeBoon v. Lancaster Jewish Cmty Ctr. Ass'n*, 503 F.3d 217, 226 (3d Cir. 2007).
[24] *See e.g., Woodell*, 357 F. Supp. 2d at 767; *N.L.R.B. v. Catholic Bishop of Chi.*, 440 U.S. 490, 506-07 (1979).
[25] *See e.g., Chronister v. Baptist Health*, 442 F.3d 648, 652 (8th Cir. 2006); *LeBoon*, 503 F.3d at 226.
[26] *See e.g., Spencer v. World Vision, Inc.*, 633 F.3d 723, 734 (9th Cir. 2010).
[27] *See e.g., Chronister*, 442 F.3d at 652.
[28] *See e.g., Catholic Charities of Maine, Inc. v. City of Portland*, 304 F. Supp. 2d 77 (D. Me. 2004)
[29] *See e.g., St. David's Health System v. United States*, 349 F.3d 232, 242 (5th Cir. 2003).
[30] *See e.g., Spencer*, 633 F.3d at 734; *Woodell*, 357 F. Supp. 2d at 767.
[31] *See e.g., LeBoon*, 503 F.3d at 226.
[32] *See e.g., id.*
[33] *See e.g., id.*

3. Colleges and Universities should not qualify for an accommodation.

The Departments must ensure that college students receive contraceptive services without cost-sharing, even if they attend a college or university that meets the accommodation's definition of "religious organization." In March 2012, HHS made clear that "[s]tudent health insurance coverage must include the preventive services specified under PHS Act section 2713 and the implementing regulations (45 CFR § 147.140)."[34] In August 2011, after receiving recommendations from the IOM, HHS determined that the list of required preventive services includes the full range of FDA-approved contraceptive methods and counseling.[35] We commend the Departments' decision to require that student health plans provide contraceptive coverage without cost-sharing.[36] The Departments' decision will increase access to essential preventive health care services, notwithstanding that HHS has determined that student administrative health fees are not cost-sharing within the meaning of the ACA. The decision reaffirms the critical need for contraceptive coverage. More than one million unintended pregnancies occur to single women in their twenties each year—many of these women are enrolled in a college or university.[37]

We accordingly strongly oppose any proposal that allows a college or university to refuse to provide contraceptive coverage to its students. Extending the accommodation to religiously-affiliated colleges and universities would undermine the health and autonomy of affected students, as well as the promise of the ACA. If the Departments nonetheless decide to extend the accommodation to colleges or universities owned or controlled by exempted religious organizations, they must ensure students attending such institutions have the same access to contraceptive coverage, without cost sharing, as students at universities that do not qualify for the accommodation. As discussed further below, the Departments should require that colleges, universities, and health insurance issuers provide students with timely, accurate, and clear information about students' contraceptive coverage without cost-sharing. Further, the Departments should make clear that students unable to access health care services, including contraceptive services and supplies, from in-network providers are entitled to access such services through local out-of-network providers without cost-sharing.

<u>RECOMMENDATION</u>: For purposes of the accommodation, the definition of "religious organization" should not include religiously-affiliated colleges and universities.

4. The Departments should not allow "religious organizations" to provide coverage for only some forms of contraceptive methods.

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[34] Student Health Insurance Coverage, 77 Fed. Reg. 16,453 (March 21, 2012) (to be codified at 45 C.F.R. pts. 144, 147, and 158).
[35] U.S. Dep't of Health & Human Servs., Health Res. & Servs. Admin., *supra* note 3.
[36] 77 Fed. Reg. 16,453.
[37] National Campaign to End Teen and Unplanned Pregnancy, *Unplanned Pregnancy Among 20-Somethings: The Full Story* (2007), http://www.thenationalcampaign.org/resources/20-somethings.aspx.

Every woman should be able to make her own decisions about whether or when to prevent pregnancy based on her own beliefs and needs, not the beliefs of her employer, college, or university. She should similarly be able to decide, based on accurate and complete information, which method of birth control is most appropriate for her. Indeed, the IOM report recognized that not all contraceptive methods are right for every woman, and that access to the full range of pregnancy prevention options would allow a woman to choose the most effective method for her lifestyle and health status.[38] The IOM accordingly recommended that women have access to the full range of FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity.

We strongly urge the Departments not to bifurcate women's contraceptive coverage. The Departments should not allow "religious organizations" to pick and choose which forms of contraception to cover. Among other things, providing coverage for certain contraceptive service under one health plan and for other methods under another plan creates administrative complexity. For example, such a rule could force health insurance issuers and TPAs working with multiple religious organizations to design numerous different plans with various permutations of contraceptive coverage. Allowing employers to split contraceptive coverage could also confuse plan participants and beneficiaries, consequently leading to gaps in access to and use of the contraceptive method most appropriate for a woman's needs.

<u>RECOMMENDATION</u>: For purposes of the accommodation, the Departments' definition of "religious organization" should exclude any religious organization that provides coverage for some, but not all, FDA-approved contraceptives.

5. The Departments must ensure that all women have timely access to covered contraceptives and receive timely and accurate notice of their right to receive contraceptive coverage without cost-sharing.

In recognition of the importance of contraception to the health and well-being of women and their families, the Departments affirmed that they "aim to maintain the provision of contraceptive coverage without cost sharing to individuals who receive coverage through non-exempt, non-profit religious organizations with religious objections to contraceptive coverage in the simplest way possible."[39] To fulfill this goal, the Departments must ensure that the accommodation is structured to provide affected women seamless access to contraceptive coverage. The accommodation should not be structured as a rider to an eligible employer's or school's health insurance package, and it should not be considered a supplemental policy or provision.

The Departments must ensure that employers, schools, and health insurance issuers make women aware that contraceptive coverage is available to them without cost-sharing. An employer or school seeking to avail itself of the accommodation must adhere to certain notice requirements. To do otherwise would allow employers, schools, and/or insurers to erect new

[38] Inst. of Medicine of the Nat'l Academies, *supra* note 5.
[39] 77 Fed. Reg. 16,501.

barriers that vastly undermine the promise of the ACA to improve the health of the nation. These notice requirements should include the following:

- Employees and students must receive prominent and conspicuous written notice of contraceptive coverage without cost sharing;
- The notice must be accessible to limited English speakers and for persons with disabilities;
- The notice must contain information about the rights of employees and students to contraceptive coverage, the availability of contraceptive coverage through a third party, as well as contact information for that third party;
- The employer or school should provide written notice in insurance enrollment materials on whether contraceptive coverage is made available by a third party;
- The employer or school must ensure that employees and students have prompt access to this information;
- Health insurers and TPAs should similarly provide such notice on health insurance cards, on separate written notices mailed to beneficiaries, and on their websites;
- The Departments should make clear that an employer, school, and/or insurer does not fulfill its notice requirements by merely providing notice in a Summary Plan Description.

Federal guidance should also prohibit the employer or university from providing misleading, inaccurate, or conflicting information to employees and students, including statements suggesting that contraceptive coverage is not available to those individuals. To this end, guidance should make clear that an employer or university is prohibited from stating or implying that an employee or student does not have contraceptive coverage. Thus, for example, the summary of benefits of coverage should not state or imply that a beneficiary in a plan subject to the accommodation does not have contraceptive coverage. Further, contraceptive coverage should not be included in the "Limitations & Exceptions" column of the chart that begins on page two of the summary of benefits and coverage or in the box entitled "Services Your Plan Does NOT Cover."

<u>RECOMMENDATION</u>: We urge the Departments to ensure that all women, including women whose employers or schools object to contraception, have seamless access to contraceptive coverage and to timely and accurate information about their health care coverage.

6. **The Departments should designate an agency to enforce and oversee the religious employer exemption and religious organization accommodation.**

The Departments should require than any entity availing itself of the exemption or accommodation submits a written certification that the organization satisfies the eligibility criteria and an acknowledgement that it will comply with the notice requirements. The entity should submit this document to an agency designated by the Departments. The Departments must also make the self-certification available for public examination. Similarly, the entity should make the self-certification available for inspection to its employees and/or students. The Departments must ensure that the public is made aware of how to access these self-certifications.

The Departments should also make a list of all organizations availing themselves of the accommodation available to the public.

The Departments must ensure a clear mechanism for a woman who believes her rights were violated to seek enforcement of her rights. The Departments must accordingly designate a federal agency to have enforcement authority. This agency would initiate and carry out its own investigations of any violations of the rules governing the religious employer exemption and/or accommodation as well as act on any individual complaints.

<u>RECOMMENDATION</u>: The Departments must enforce and oversee the exemption and accommodation.

7. **State contraceptive coverage laws that are more protective of access to contraceptive coverage should prevail; the federal contraceptive coverage requirement should preempt state contraceptive coverage laws that undermine federal law and policy.**

Twenty-eight states already require employers to provide contraceptive coverage; the ACA seeks to ensure that women across the country will have the same benefits. Some of these laws are more protective of women's health care needs than the federal requirements. A state law that does more to ensure women's access to contraceptive coverage—for example, by not exempting any religious employers—is not preempted by the contraceptive coverage requirement. Because such a law is more protective of women's health than the federal requirement and helps more consumers, it does not prevent, but in fact furthers, the application of the ACA.[40] The Departments appropriately recognize that these state laws "will continue."[41]

However, we are concerned that the Departments appear to unnecessarily limit the continuation of more protective state laws to a "transition period."[42] This appears to be a reference to the temporary enforcement safe harbor period.[43]The preemption principles of the ACA are not limited to any particular time period. The Departments should clarify that appropriate application of the ACA's preemption provisions requires that state contraceptive coverage laws that are more protective of consumers (i.e., contain a narrower religious employer exemption and do not include an accommodation) and ensure that more women have

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[40] "State insurance laws that are more stringent than the Federal requirements are unlikely to 'prevent the application of' the Affordable Care Act, and be preempted." *Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act,* 75 Fed. Reg. 41,726, 41,739 (July 19, 2010) (to be codified at 45 C.F.R. pt. 147) (referring to the "preemption provisions" of § 731 of ERISA and § 2724 of the PHS Act) (implemented in 29 C.F.R. § 2590.731(a) (2011) and 45 C.F.R. § 146.143(a) (2010))).

[41] 77 Fed. Reg. 16,501.

[42] *Id.*

[43] Ctr. for Consumer Info. & Ins. Oversight & Ctrs. for Medicare & Medicaid Servs., Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, http://cciio.cms.gov/resources/files/Files2/02102012/20120210-Preventive-Services-Bulletin.pdf.

contraceptive coverage included in their employee benefit plan will not be preempted and will continue to apply beyond the "transition period."

Some state laws, on the other hand, have religious employer exemptions that are broader than the federal contraceptive coverage requirement's exemption, allowing more employers to refuse this critical coverage. The Departments appropriately recognize that broader religious employer exemptions must be "narrowed to align with that in the final regulations."[44] Such a result is required by the preemption provisions of the ACA, which dictate that state insurance laws that "prevent the application of a requirement" of the ACA are preempted.[45] Allowing more employers to refuse contraceptive coverage would leave more individuals without coverage of this critical service, force them to pay out-of-pocket, and put them at risk for unintended pregnancies, with the concomitant risks of poor maternal and infant health outcomes, particularly for women experiencing health disparities. These state religious exemption laws prevent the application of the federal contraceptive coverage requirement and are therefore preempted by it.

Finally, the Departments should address the interaction of state contraceptive coverage laws and the federal contraceptive coverage requirement with respect to grandfathered plans. Grandfathered plans are not required to comply with § 2713 of PHS Act. However, grandfathered plans are, for the most part, subject to state contraceptive coverage laws. The Departments should clarify that grandfathered plans must continue to comply with the applicable state contraceptive coverage laws even though they are not required to comply with the federal contraceptive coverage requirement.

CONCLUSION

We urge the Departments to consider our recommendations to ensure that all women who are impacted by the ANPRM receive seamless coverage for contraception without cost-sharing. If you should have questions about these comments, please contact Susan Berke Fogel at (310) 204-6010 or fogel@healthlaw.org. Thank you for your consideration.

Sincerely,

Emily Spitzer
Executive Director

Attachment: National Health Law Program, *Health Care Refusals: Undermining Quality Care for Women*

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77 Fed. Reg. 16,501.

[45] *See* 75 Fed. Reg. 41, 739 (referring to "the preemption provisions of § 731 of ERISA and § 2724 of the PHS Act (implemented in 29 C.F.R. § 2590.731(a) (2011) and 45 C.F.R. § 146.143(a) (2010))).