June 19, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9968-ANPRM
P.O. Box 8016
Baltimore, MD 21244-185

Submitted electronically at www.regulations.gov

Subject: ANPRM: Certain Preventive Services Under the Affordable Care Act, CMS-9968-ANPRM, Docket ID: CMS-2012-0031

Raising Women's Voices for the Health Care We Need (RWV), a national initiative representing diverse women, families and communities throughout the United States, is submitting these comments on the Advance Notice of Proposed Rulemaking (ANPRM) on "Certain Preventive Services Under the Affordable Care Act," published in the Federal Register on March 21, 2012 by the Department of the Treasury, Department of Labor, and Department of Health and Human Services (Departments).
Early in the health reform process, women's health advocates identified the need for affordable insurance coverage of comprehensive contraceptive services. RWV advocated for this coverage throughout the legislative development of the ACA, and applauded the inclusion of the Women's Health Amendment in the Affordable Care Act (ACA). We strongly support the rule finalized on February 15, 2012 requiring insurance companies to cover contraceptive services without co-payments,[1] and hailed it as an historic advance for women's health.

The importance of this provision of the law has been affirmed again and again by medical and public health experts, including in the recommendations of the IOM committee on Clinical Preventive Services for Women: Closing the Gaps. Affordable contraceptive coverage is a vital component of health care and must be available to any woman of reproductive health age, no matter where she works or goes to school.

The religious employer exemption must not be expanded
The inclusion in the rule of an exemption which allows certain religious employers to refuse to provide contraceptive coverage to their employees will have the unfortunate consequence of denying some women access to services, based on the beliefs of their employers. In September 2011, we submitted comments opposing the exemption and describing the damaging impact it would have on the health and well-being of women and their families. Some who oppose the contraceptive coverage policy have urged the Departments to expand the exemption so that more employers will be able to deny this important coverage to the women who work for them. We strongly urge the Departments to implement the law and the regulations requiring contraceptive coverage without any expansion of the

[1] Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. at 8,725.

exemption, so as to ensure that the number of women who are denied the contraceptive care they need is not expanded.

Although the stated purpose of the ANPRM is to seek comment on the *accommodation* proposal, it also seeks comment on whether an *exemption* should be made for "certain religious health insurance issuers or third-party administrators."[2] This would significantly expand the definition of religious employer beyond the one articulated in the final regulations.[3] Expanding the religious exemption in any way would undermine the important women's health goals of the ACA and the Women's Health Amendment.

Just as there should be no formal expansion of the religious employer exemption, the Departments should not extend the terms of the exemption informally to other employers that do not independently meet all four criteria to qualify for the religious employer exception on their own. Language included in the ANPRM seems to suggest that an organization, such as a Catholic elementary school, that would not qualify on its own for the religious employer exemption can simply enroll its employees in a qualified religious employer's health plan and thereby deny its employees contraceptive coverage.[4] This kind of back-door denial sacrifices women's health and the health of their families, undermines gender equality, and imposes the religious beliefs of the organization on participants and beneficiaries who might not share them.

Public family planning and public insurance programs are not a workable substitute

Those who oppose requiring insurers to provide contraceptive coverage without co-pays have argued that women's needs for contraceptive care can be met through existing government programs, such as the Title X family planning program and Medicaid. This is an unworkable, impractical proposal that cannot be viewed as a serious solution to a very serious unmet health care need. While these programs provide excellent services to millions, they are already overstretched and unable to fully meet the demand for contraceptive care.

Opponents of the policy have also proposed that the government, itself, should pay for and provide contraceptive coverage to employees of religiously-affiliated institutions, if the employees desire that coverage. This so-called solution would be very bad public policy, amounting to a windfall for religious institutions – a government subsidy not available to other employers.

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[2] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,507.

[3] A "religious employer" is defined as an employer 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 under section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) refer to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, Interim Final Rules, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011). This definition was finalized without change. Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,727 (Feb. 15, 2012) (to be codified at 45 C.F.R. pt. 147).

[4] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,502.

The proposed accommodation

We are concerned about the Departments' intention, put forth in the ANPRM, to provide an accommodation to certain additional religiously-affiliated employers that object to contraceptive coverage for religious reasons, but do not qualify for the previously established religious employer exemption. ***We are opposed to any accommodation which would place new obstacles in the path of a woman seeking the contraceptive care she needs to preserve and maintain her own health, or the health and well-being of her family***.

If the Departments move forward with the accommodation proposal, we want to ensure that they do so in a manner which ensures that all women who get health insurance from an accommodated employer receive the benefits of coverage for contraceptive care without a co-pay and without any additional barriers or burdens. Any accommodation must ensure that women receive coverage which provides them with access to the seamless care they are entitled to under the law. For this reason, we offer the following comments on the ANPRM.

The Departments should make clear that, for purposes of the accommodation, for-profit enterprises, health insurance issuers, and third party administrators (TPAs) are not religious organizations.

The ANPRM states it is intended to establish a way to accommodate *religious organizations* that object to the coverage of contraceptive services for religious reasons and that are not exempt, while still ensuring that their employees have insurance coverage for the full range of preventive services required by the ACA. For-profit businesses, health insurance issuers and third party administrators engage in commercial activities and serve commercial purposes. Their purpose is not religious exercise, and they should not be eligible for any accommodation that relieves them of the obligation to comply with the contraceptive coverage provisions of the law.

The Departments should not permit employers to use the accommodation to avoid providing coverage for a selected subset of contraceptives.

The Departments seek comment on whether religious organizations should be allowed to qualify for the accommodation with respect to some forms of contraception, while providing coverage for other forms of contraceptives without cost-sharing. We strongly urge the Departments not to permit such a practice which would undermine the goal of the contraceptive coverage requirement and create unnecessary complexity and confusion.

The preventive health services provision of the ACA was created to eliminate financial barriers to getting proven preventive care. The guidelines adopted by the Department of Health & Human Services in August 2012 state that women's preventive health care includes the full range of contraceptive methods approved by the U.S. Food and Drug Administration (FDA).[5] Allowing religious organizations to provide coverage for only certain types of contraceptives would perpetuate, for some women, the unacceptable status quo in which economic obstacles stand in the way of a woman's ability to get the services and care she needs to preserve her health, have healthy pregnancies and have healthy babies.

Organizations that provide coverage for some contraceptive methods, but not all (most often, emergency contraception and IUDs) often claim incorrectly that those methods are "abortifacients."[6]

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[5] "Women's Preventive Services: Required Health Plan Coverage Guidelines," Health Resources and Services Administration, http://www.hrsa.gov/womensguidelines/.

[6] *See, e.g.,* Complaint at 12-13, Belmont Abbey College v. Sebelius, 1:11-cv-01989 (D. D.C. filed Nov. 10, 2011).

This claim is at odds with long-established science relating to contraception and pregnancy. The medical and scientific communities define abortion as the termination of an established pregnancy (i.e., when a fertilized egg implants in the uterus).[7] A refusal to provide insurance coverage of certain forms of contraception based on a misunderstanding of science is not an objection based on religious beliefs and should not be accommodated.

Furthermore, allowing coverage of a select subset of contraception would create administrative complexity, potentially requiring health insurance issuers and TPAs to design numerous different plans with various permutations of contraceptive coverage. It would also increase the potential for confusion among women and barriers to use of the contraceptive method most appropriate for a woman's needs.

Finally, we were dismayed to see the ANPRM state that the contraceptive coverage requirement "excludes items and services such as vasectomies and condoms," apparently on the grounds that those items and services are used by men, rather than by women. Medicaid and other federal program allow coverage and provision of male condoms for female beneficiaries. Despite being used by men, these contraceptive options offer preventive health benefits to men's female partners. Furthermore, because vasectomy is less expensive, less invasive and has less risk of complications than tubal ligation, imposing cost-sharing on vasectomy but not on tubal ligation would actually undermine women's health. We urge the Departments to give serious consideration to the question of whether these items and services are excluded from the contraceptive coverage requirement and to open the question for public comment.

Women whose employers choose to use the accommodation must receive contraceptive coverage without any additional premium cost or co-pays.

The Departments clearly state in the ANPRM that there must "be no premium charge for the separate contraceptive coverage" when participants and beneficiaries receive coverage through the accommodation.[8] Furthermore, in enacting the ACA, the Congress determined that coverage of recommended preventive services without cost sharing is necessary to achieve basic health coverage. To comply with the Departments' direction and the intent of the Congress, the accommodation must not impose any extra financial burden on a woman who wants contraceptive coverage, over and above the amount, if any, she pays for the rest of her insurance coverage. This prohibition on a premium charge for contraceptive coverage must apply both to employers and insurers. Failing to meet this standard would undercut President Obama's guarantee that "women who work at these institutions [that qualify for the accommodation] will have access to free contraceptive services, just like other women, and they'll no longer have to pay hundreds of dollars a year that could go towards paying the rent or buying groceries."[9]

Contraceptive coverage must be provided seamlessly -- automatically and directly, without special enrollment or delay.

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[7] *See* 45 C.F.R. § 46.202(f) (2012) (defining pregnancy as beginning after implantation); THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, INDUCED ABORTIONS, *available at* http://www.acog.org/~/media/For%20Patients/faq043.pdf?dmc=1&ts=20120618T1001293688 (defining abortion as a procedure to end a pregnancy).

[8] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,503.

[9] Press Release, President Barak Obama, Remarks by the President on Preventative Care (Feb. 10, 2012), http://www.whitehouse.gov/the-press-office/2012/02/10/remarks-president-preventive-care.

We strongly support the Departments' statement that when an employer chooses to use the accommodation, contraceptive coverage must be provided "automatically to participants and beneficiaries covered under the organization's plan (for example, without an application or enrollment process)."[10] Any accommodation must be structured so that it provides seamless and timely access to contraceptive coverage in order to fulfill the goals of the law's preventive services provision, as well as other provisions of the ACA and other federal laws prohibiting discrimination in benefits.

A special enrollment period, delay in access to coverage, separate approval process or any other impediment built into the structure of the accommodation would create an unreasonable barrier and impede timely access to contraception, prohibited under Section 1554 of the ACA.[11] Additionally, if the accommodation is structured in a way that allows the continuation of discriminatory health care policies and practices that unfairly burden on women, this would be contrary to various prohibitions on sex discrimination in the provision of health care programs and benefits.[12,13,14]

The accommodation must protect the privacy of women with contraceptive coverage and who use contraceptive services.

We strongly support the goal of ensuring that any accommodation "protect[s] the privacy of participants and beneficiaries covered under the plan who use contraceptive services," as stated in the ANPRM.[15]

Women whose employers make use of the accommodation must receive timely, accurate, and clear information about their contraceptive coverage without cost-sharing.

We support the importance placed by the Departments on requiring health insurance issuers and Third Party Administrators (TPAs) to provide women with notice about the contraceptive coverage without cost-sharing that is included in their plan. This notice must be timely, accurate and clear as well as delivered by multiple methods, to ensure that women are adequately informed of this new coverage. Strong rules regarding notice of contraceptive coverage are necessary to ensure that women know their insurance will cover these services.

For example, when a health insurance issuer or TPA sends an insurance card directly to the participants and beneficiaries of the plan, the Departments should require a clear, obvious notice indicating that the individual has contraceptive coverage without cost sharing. Existing participants and beneficiaries, who already have an insurance card, should get a separate notice with the same information. In both cases, the notice should include instructions about how women can get more information about the coverage,

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[10] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,505.

[11] Section 1554 of the ACA, entitled Access to Therapies, prohibits the Secretary from promulgating "any regulation that—

(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
(2) impedes timely access to health care services."

[12] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557 (2010) (to be codified at 42 U.S.C. § 18114).

[13] Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (codified as amended in scattered sections of 2 U.S.C., 28 U.S.C., & 42 U.S.C.).

[14] 20 U.S.C. 1681 (1972).

[15] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,505.

by contacting the insurer or TPA to request more information or through information posted on the insurer's or TPA's website.

Offering information about contraceptive coverage on the health insurance issuer's website is useful, but not in and of itself sufficient notice. Providing information about contraceptive coverage on a website -- without specifically directing participants and beneficiaries to the webpage including the information -- should not be considered adequate notice of coverage.

The Departments should also require that women receive accurate information about their contraceptive coverage in any communications from the health insurance issuer, employer, plan sponsor, or third party administrator. The Departments should take steps to guarantee that all applicable state and federal notice or communication requirements accurately reflect the coverage that an individual is entitled to and do not convey conflicting information. For example, under the ACA, all group health plans and health insurance issuers offering group or individual health insurance coverage must provide a summary of benefits and coverage (SBC) to all applicants, enrollees, and policyholders or certificate holders.[16] The SBC is required by statute to "accurately describ[e] the benefits and coverage under the applicable plan or coverage."[17] The Departments should ensure that the SBC does not state or imply that an individual in a plan receiving an accommodation does not have contraceptive coverage. For example, contraceptive coverage should *not* be included in the "Limitations & Exceptions" column of the chart that begins on page two of the SBC. Similarly, contraceptive coverage should *not* be listed in the box "Services Your Plan Does NOT Cover."

Requiring this notice and communication does not restrict a religious organization's freedom of speech regarding contraception. The religious organization is free to communicate its views about contraception to employees or students through other avenues.

Women whose employers make use of the accommodation must not lose out on critical protections, like continuation coverage, appeals and external review, and the right to see an OB/GYN provider without a referral.

The Departments explain in the ANRPM that they are considering adding contraceptive coverage to the types of excepted benefits in the individual market and seek comment on whether and how to structure such a change and what Public Health Service (PHS) Act protections should apply.[18] Any provisions of the PHS Act that are designed to protect enrollees' access to benefits covered by a plan should apply to contraceptive coverage provided through the accommodation.

For example:

- There should be no annual or lifetime dollar value maximums on essential health benefits.[19]
- Women should retain their right to internal appeals and external review, including all accompanying notice requirements, for contraceptive coverage.

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[16] Patient Protection and Affordable Care Act § 1001

[17] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,505.

[18] *Id.* at 16,506.

[19] The preventive services required by § 2713 are included as part of the essential health benefit package. U.S. Dep't Health & Human Services, *Frequently Asked Questions on Essential Health Benefits Bulletin*, http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf, (last visited June 4, 2012).

- Women seeking contraception services should be allowed direct access to any primary care provider in the network, including any ob-gyn provider, and without a referral.
- The contraceptive coverage should be incorporated into the Summary of Benefits and Coverage by not listing contraceptive services as excluded by the plan, as explained above.

Additionally, if a woman is eligible for and enrolls in COBRA continuation coverage, [20] then that coverage must include the contraceptive coverage either as part of the plan or through the accommodation. She should not be required to take any additional steps, including no requirement to actively choose to have contraceptive coverage included, and there should be no additional premium.

These recommendations represent a minimum starting point, not an exclusive list. We urge the Departments to be very careful in crafting any definition of the contraceptive coverage as excepted benefits to ensure that women do not lose any protections they would receive without an accommodation.

Any accommodation offered to universities and colleges for their student health plans must take into account and resolve the barriers and challenges facing students seeking contraception.
If the Departments extend the accommodation to student health plans, it must ensure that students have seamless access to contraceptive coverage without cost sharing. Similarly, the Departments should ensure that health insurance issuers provide students with timely, accurate, and clear information about the contraceptive coverage without cost-sharing.

Additionally, any such accommodation must take into account the unique barriers and challenges facing students who seek contraception. Students who attend a college or university that does not provide contraception through its student health center for religious reasons are likely to face especially significant difficulties in accessing contraception. Many students lack cars or access to reliable public transportation necessary to get to an off-campus provider, and this can significantly compromise their ability to access contraceptive care. Furthermore, because student health plans often include only student health centers and university hospitals in the plan network, students at schools which do not provide contraceptive care at the student health center or university hospital are commonly burdened with additional costs associated with getting contraceptive care from an out-of-network provider. For these reasons, we urge the Departments to clarify that when students are unable to obtain preventive services at an in-network provider, students will be permitted to access care, including contraceptive services, through an out-of-network provider at no cost-sharing.[21]

We strongly support the Department's application of preemption principles that allow the continued enforcement of state contraceptive coverage laws that are more protective of access to contraceptive coverage and preempt those that undermine the federal contraceptive coverage requirement.
Twenty-eight states have existing legal requirements mandating coverage of contraception in health insurance plans. These state laws were enacted to remedy disparities in women's access to critical health care, and they have taken important steps toward meeting women's unique health care needs and improving the health of both women and infants. The new federal contraceptive coverage

[20] 29 U.S.C. § 1161.
[21] We urge the Departments to clarify that the § 2713 coverage and no cost-sharing requirements apply to services obtained from any provider when in-network providers are unwilling or unable to provide the services, for both students and any other individual enrolled in a non-grandfathered plan.

requirement will further advance these goals, helping to fill in gaps in coverage and further reducing disparities by providing women broad access to contraceptive coverage without cost-sharing.

The preemption provisions of the ACA dictate that state insurance laws that "prevent the application of a requirement" of the ACA are preempted.[22] Therefore, the Departments appropriately recognize that state laws which include religious employer exemptions broader than the federal exemption must be "narrowed to align with that in the final regulations."[23] Allowing the broader exemption to stand would undermine the intended purpose of preventive health provision of the ACA, leaving more women without contraceptive coverage, forcing them to pay out-of-pocket, and putting them at risk for unintended pregnancies, with the concomitant risks of poor maternal and infant health outcomes. These state laws prevent the application of the federal contraceptive coverage requirement and are therefore preempted by it.

By contrast, a state law which ensures that more women have contraceptive coverage than would have it under the federal law – for example, by not exempting any religious employers – is not preempted by the federal contraceptive coverage requirement. Because such a state law is more protective of women's health than the federal requirement and helps more women, it does not prevent, but in fact furthers, the application of the Affordable Care Act.[24]

The Departments should make clear that these preemption principles will apply beyond the temporary enforcement safe harbor period and clarify that grandfathered plans must continue to comply with applicable state contraceptive coverage requirements.
The Departments appropriately recognize that state contraceptive coverage laws "will continue."[25] However, the Departments appear to unnecessarily limit the continuation of more protective state laws to a "transition period,"[26] which presumably refers to the temporary enforcement safe harbor period. The preemption principles of the ACA are not limited to any particular time period. For this reason, the Departments should clarify that the preemption principles it recognizes – that those laws which protect more women will not be preempted while those that protect fewer will be – will continue to apply beyond the transition period.

Finally, the Departments should address the interaction of state contraceptive coverage laws and the federal contraceptive coverage requirement with respect to grandfathered plans which are not required to comply with the preventive health provisions of the law, including the contraceptive coverage requirement. Grandfathered plans are, for the most part, subject to state contraceptive coverage laws, and the Departments should clarify that grandfathered plans must continue to comply with the applicable state contraceptive coverage laws.

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[22] *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, Interim Final Rules, 75 Fed. Reg. 41,726, 41,739 (July 19, 2010)(referring to "the preemption provisions of section 731 of ERISA and PHS Act section 2724 (implemented in 29 C.F.R. § 2590.731(a) (2011) and 45 C.F.R. § 146.143(a) (2010))").
[23] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,508.
[24] *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, Interim Final Rules, 75 Fed. Reg. 41,726, 41,739 (July 19, 2010) (referring to 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.")
[25] Certain Preventative Services Under the Affordable Care Act, 77 Fed. Reg. at 16,508.
[26] *Id.*

The Departments should provide enforcement and oversight of the preventive services requirement of the ACA overall, and of the religious employer exemption and religious organization accommodation in particular.

The ANPRM does not address the question of how the Departments will enforce or provide oversight to ensure compliance with the accommodation. Nor has this been addressed in other regulations for the preventive health provision of the ACA. The Departments should adopt mechanisms for oversight and enforcement of all of the preventive services coverage provisions, including the religious employer exemption and any accommodation adopted for religious organizations. Those processes should allow consumers to issue complaints and make appeals when they are inappropriately denied access to services to or required to absorb some of the cost of protected services and supplies. To encourage compliance, the Departments should provide technical assistance and education to health plans, health care providers, pharmacies, and the general public. Moreover, with respect to the exemption and accommodation from contraceptive coverage, we urge the Departments to require that any entity seeking to avail itself of the exemption or accommodation send a written statement certifying its compliance to an appropriately designated enforcement body. The enforcement body should maintain a file of all entities invoking the exemption or accommodation, and make that information available to the public. This will provide transparency to the public about which entities have invoked the exemption or accommodation.

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Thank you for the opportunity to submit these comments. We hope you will find them useful.

Sincerely,

Raising Women's Voices for the Health Care We Need

Raising Women's Voices for the Health Care We Need is a national initiative coordinated by the Black Women's Health Imperative, the National Women's Health Network and the MergerWatch Project, with 22 regional coordinators across the country.