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December 5, 2017

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

Subj: Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, RIN 0938-AT46

Dear Sir or Madam:

The National Association of Catholic Nurse U.S.A (NACN-USA) is the national professional organization for Catholic nurses in the United States. Representing hundreds of nurses of different backgrounds, the NACN-USA promotes education in Catholic nursing ethics, nurtures spiritual growth, provides guidance, support and networking for Catholic nurses, nursing students, and others who support our mission and objectives. The NACN-USA is approved by the U.S. Conference of Catholic Bishops and is a part of the International Catholic Committee of Nurses and Medico-Social Assistants, which collaborates with the Holy See and its Dicastery for Promoting Integral Human Development. The NACN-USA submits the following comments on the interim final rules, published at 82 Federal Register 47838 (October 13, 2017), on moral exemptions and accommodations for coverage of certain preventive services under the Affordable Care Act (ACA).

The NACN-USA is pleased to see the expansion in these interim final rules of exemptions to protect the moral convictions for certain entities and individuals whose health plans are subject to the contraceptive mandate issued pursuant to the ACA. This is consistent with Congress' history of supporting moral convictions alongside protection for religious beliefs regarding contraception, sterilization and abortion, as evidenced by long-standing laws such as the Church and Weldon Amendments. For this we are grateful.

However, as explained in NACN-USA's comments on the interim final rules published at 82 Federal Register 47792 (October 13, 2017) on religious exemptions, we are again concerned that the present interim final rules allow the Health Resources and Services Administration (HRSA) the option to include contraceptives as a preventive service when, in fact, they are not.

As directed by the Department's interim final rules, HRSA was charged with developing guidelines with respect to preventive care and screenings authorized by section 2713(a)(4) of the Public Health Service Act. In developing those guidelines, HRSA looked to a report on women's

preventive services issued July 19, 2011 by the Institute of Medicine (IOM) which recommended coverage of the full range of FDA approved contraceptive methods, including methods with abortifacient potential, sterilization procedures, and patient education and counseling for women with reproductive capacity. It is important to note that this recommendation was not unanimous among members of the IOM, as described at 82 Fed. Reg. at 47841, who voiced concern over the safety and lack of evidence of the preventive nature of contraceptives. Still, HRSA proceeded to authorize contraceptives as mandated preventive services despite the objections.

The NACN-USA is baffled as to why the Government would ignore legitimate concerns and mandate that a Group 1 carcinogen that is also associated with life-threatening cardiovascular complications would be made available to the public.¹ Surely, once a woman is diagnosed with cancer or paralyzed by a stroke it comes as no consolation to know that this came about with no cost sharing on her part other than her own tax dollars.

The NACN-USA is further perplexed by the statement that the Government wishes to better balance its interest in promoting coverage for contraceptive and sterilization services with its interest in providing conscience protections for individuals and entities with sincerely held moral convictions. While it is clearly appropriate for the Government to provide conscience protection for the public, it is clearly inappropriate for the Government to promote services that place the public at risk of disease and disability. Why would the Government have an interest in promoting contraception and sterilization among the public in the first place?

¹ Rebecca Peck & Charles W. Norris, *Significant Risks of Oral Contraceptives (OCPs): Why This Drug Class Should Not Be Included in a Preventive Care Mandate*, 79 *Linacre Quarterly* 41, 42 (Feb. 2012), <https://familyplanning.net/sites/default/files/Significan-Risks-of-Oral-Contraceptives-OCPs-Why-This-Drug-Should-Not-Be-Included-In-a-Preventive-Care-Mandate.pdf>.

The World Health Organization Department of Reproductive Health and Research, *The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment*, September 2005, http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf.

The American Cancer Society, *Known and Probably Human Carcinogens*, 2017,

<https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html>

Lidegaard, Ø., Løkkegaard, E., Svendsen, A. L., & Agger, C. (2009). Hormonal contraception and risk of venous thromboembolism: national follow-up study. *The BMJ*, 339, b2890.

<http://www.bmj.com/content/bmj/339/bmj.b2890.full.pdf>.

Van Hylckama Vlieg, A., Helmerhorst, F. M., Vandenbroucke, J. P., Doggen, C. J. M., & Rosendaal, F. R. (2009).

The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study. *The BMJ*, 339, b2921. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2726929/>

Vinogradova, Y., Coupland, C., & Hippisley-Cox, J. (2015). Use of combined oral contraceptives and risk of venous thromboembolism: nested case-control studies using the QResearch and CPRD databases. *The BMJ*, 350, h2135.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4444976/>

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Gillum, L.A., Mamidipudi, S.K., Johnston, S.C., (2000). *Ischemic stroke risk with oral contraceptives: A meta analysis*. *JAMA* 2000 Jul; 284(1), 72-78. <https://www.ncbi.nlm.nih.gov/pubmed?term=10872016>

Lidegaard, Ø., Løkkegaard, E., Jensen, A., Skovlund, C.W., Keiding, N. (2012). *Thrombotic stroke and myocardial infarction with hormonal contraception*. *N Eng J Med*. 2012; 366(24):2257.

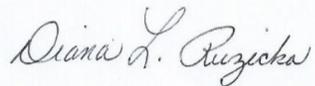
<https://www.nejm.org/doi/pdf/10.1056/NEJMoal111840>

Except for contraception, all the other services listed by HRSA under the Women's Preventive Services Guidelines are evidence-based and pose no risk to the health and well-being of women.² This is as it should be. At the risk of appearing naive, the NACN-USA can come to no other conclusion than that the decision to include contraceptives as a preventive service is based not on scientific fact but on ideology. Governance of health care that adheres to ideology and ignores scientific fact places the health and well-being of the public at risk.

The NACN-USA is grateful to see the expansion of exemptions in these interim final rules to protect the moral convictions of those having objections to the contraceptive coverage mandate. For as it can be seen from the dissent of members of the IOM itself, as expert advisors to HRSA, objections are not restricted to those that are religiously based but can and should be based on science and reason. The mandate should be rescinded.

Thank you for the opportunity to comment.

In His Holy Name,

A handwritten signature in cursive script that reads "Diana L. Ruzicka". The signature is written in black ink on a white background.

Diana Ruzicka, RN, MSN, MA, MA, CNS-BC
Colonel, U.S. Army Retired
President, National Association of Catholic Nurses, U.S.A

² Health Resources and Services Administration (October 2017). *Women's Preventive Service Guidelines*. <https://www.hrsa.gov/womens-guidelines-2016/index.html>