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Comment on Proposed Rule: Enhancing Coverage of Preventive Services Under the Affordable Care Act
RIN 0928-AV57 (HHS); 1210-AC25 (DOL); 1545-BR35 (TREAS)
December 20, 2024

The American Association of Prolife Obstetricians and Gynecologists (AAPLOG) is a fifty-year-old professional medical organization that represents more than 7,500 women's healthcare professionals across the country. We were founded to represent the vast majority of OB/GYNs who do not perform induced abortion, which intends the death of our fetal patients. We recognize based on the medical evidence that this practice is not healthcare, and we are passionate about providing excellent, evidence-based healthcare to ALL our patients.

Over the counter (OTC) contraception is not good public policy. We are concerned that this policy : 1) undermines the key role of physicians in protecting women's health, 2) undermines informed consent about the embryocidal potential of hormonal contraceptives, and 3) advances harmful trends in American healthcare.

Undermining the key role of physicians in protecting women's health

The proposed rule is unfortunately following the trend of removing doctors from crucial touch points with their patients, thereby jeopardizing excellent health care for women by removing the ability to have important conversations surrounding our patients' healthcare decisions.

The proposed rule will allow – and incentivize -- women to obtain and use hormonal contraceptives without first consulting their physician. Rather than offering women more freedom, this change will disempower them by robbing them of the doctor-patient relationship and the expert guidance and support that comes with it as they make consequential healthcare decisions, leaving them vulnerable to negative health outcomes.

For example, in the status quo, the prescription requirement for these drugs is the primary factor that motivates many women to visit their gynecologist for well-woman exams. Removing this requirement will allow women to bypass these physician visits, causing many to forgo them altogether. These women will miss out on essential screenings as well as the chance to discuss health concerns and pursue diagnoses and effective treatments. As a result, serious reproductive health conditions such as endometriosis and polycystic ovarian syndrome (PCOS), along with other chronic conditions like hypertension or

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diabetes, which impact a significant percentage of the female population, may continue untreated, grow worse, and negatively impact their quality of life.

Furthermore, the easy availability of hormonal contraceptives will incentivize women to use these drugs to treat deeper underlying health conditions rather than seeking diagnoses and effective treatments that address root causes. Conditions like endometriosis and PCOS are already undertreated, as women are often prescribed contraceptive drugs to treat their symptoms with little effort made to discover and address root causes. Removing the prescription requirement for these drugs will only worsen this trend as physicians are not even given the chance to further investigate their patients' symptoms and potentially make a more accurate diagnosis which may require a completely different treatment.

In addition to undermining women's relationships with their family physician or gynecologist, removing the prescription requirement will also cut off many women's relationship with their pharmacist, robbing them of the chance to have an expert review their other medications to screen for possible significant drug interactions or contraindications to the contraceptive.

Cutting medical professionals out of the process of obtaining hormonal contraceptives will also leave women vulnerable to improper use and abuse of these drugs. These medications are not benign, with significant side effects and risks that vary by drug. Using the wrong drug can negatively impact women's physical and mental health, as well as breastfeeding and other reproductive goals. It will be difficult for women to discern which drug, if any, is best for them without the help of a medical professional who can allow them to make a fully informed decision by discussing the benefits, risks, contraindications, etc. of each option – specific to their individual clinical scenario. Additionally, without a prescription requirement, these drugs can more easily be stockpiled and used beyond their expiration date.

They can also be obtained by people with abusive intent, such as to secretly give women these drugs without their consent. This country has already seen multiple cases of abusers attempting to terminate women's pregnancies by giving them abortion drugs without their consent; a similar risk exists to making contraceptive drugs available without a prescription.

Last year, the U.S. Food and Drug Administration approved OTC birth control for the first time. This progestin-only contraceptive method includes no age limit or restriction, no parental consent needed, and no doctor as part of the conversation. This classification and unregulated access already lacks truly informed consent, is not good medicine, and is dangerous for women and girls' health and safety.

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Undermining informed consent about the embryocidal potential of hormonal contraceptives

AAPLOG has a moral opposition to any practice that intentionally ends the life of a human being. AAPLOG is committed to a philosophy of healthcare that recognizes human beings at all stages of development -- from the moment of fertilization to natural death -- as valuable. The scientific evidence is exceedingly clear that at the moment of fertilization, a new distinct human being comes into existence – NOT, as some may erroneously assert, after implantation. For this reason, we find it essential that women be informed about the potential for hormonal contraceptives not only to prevent fertilization, but also to end the life of a newly-fertilized human organism by preventing implantation into the uterus. While this would not apply to every contraceptive, it certainly appears to apply to some, including some encompassed in this proposed rule. Removing the prescription requirement robs women of the opportunity to discuss and gain awareness of this risk with their physician.

In our Committee Opinion "Embryocidal Potential of Modern Contraceptives"[1], we detail the scientific evidence available on the possible post-fertilization effects of hormonal contraceptives and emergency contraception. The full Committee Opinion is attached to this comment, but quoting from it:

The mechanism of action of contraceptive drugs and devices form an essential part of informed consent for patients considering various methods of family planning…AAPLOG members take different positions on the philosophical issue of contraception use per se…

There are three reasons for concern about embryos conceived during the use of a particular contraceptive drug or device:

1. All contraceptive drugs and devices "fail" at a certain rate. As noted in a recent paper, "Unintended pregnancies occur with all contraceptive methods, including IUDs. This provides incontrovertible evidence that fertilization and implantation can occur, albeit rarely, with modern methods of contraception."

2. Since pregnancies can and do occur during the use of all contraceptive drugs and devices, then we know by definition that fertilization, which marks the beginning of an embryonic human organism, can and does happen with all contraceptive drugs and devices since by definition an embryo must be created for pregnancy to occur. That means embryos are created at a certain rate with all contraceptive drugs or devices.

[1] AAPLOG Committee Opinion 7: "Embryocidal Potential of Modern Contraceptives" https://aaplog.org/wp-content/uploads/2024/05/Committee-Opinion-updated.pdf

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3. The contraceptive drug or device will create a certain environment for the embryos created during their use. This environment may adversely affect embryo survival prior to and up to the point of yielding a positive pregnancy test at the end of the cycle (the contraceptive efficacy end point).

For progestin-only pills or continuous progesterone, "…estrogen stabilization of the endometrial lining is absent. Progestin-only contraceptives induce a thin friable endometrium…There is much more reason for concern about embryo formation and loss with progestin-only contraceptives than with combined hormonal contraceptives because of the much greater incidence of sonographically documented follicular rupture in users of progestin-only contraceptives."

Concerns with progestin-only contraceptives

In summary, with the exception of Depo-Provera, a significantly greater number of women appear to have follicle rupture with the progestin-only contraceptives than with combined hormonal contraceptives. In order to explain the efficacy of progestin-only contraceptives, mechanisms of action other than preventing the release of eggs must play a major part in the mechanism of action.

Women on continuous progestin-only contraceptives, with the exception of Depo-Provera users, are at increased risk of ectopic pregnancy.

There are no direct studies looking at miscarriage rate on the progestin-only contraceptives. However, the few studies suggesting an increased loss rate for women after use of combined hormonal contraception implicate the progestin component of the COC. Progestins cause profound changes and atrophy of the endometrium, changes which may take some time to resolve after discontinuing progestin-only contraceptives. Support for this idea is the known delay in return to fertility, i.e., the delay in being able to achieve and sustain a positive pregnancy test, for several months after the long term use of continuous progestin-only contraceptives.

Emergency contraceptives (Plan B and Ella):

Emergency contraceptives include both high dose progestins (Plan B, Next Choice) as well as progesterone receptor antagonists RU-486 (Mifeprex) and ulipristal (Ella).

High dose progestin (Plan B) - Although changes in the endometrium with high dose progestins are not as dramatic as with progesterone blockers like Ella, high dose progestins like Plan B can cause endometrial changes which can make implantation more difficult.

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Progesterone blockers directly block the effects of progesterone on the cells of the endometrial lining. So the changes that progesterone must make in the lining to allow the embryo to implant are directly blocked by progesterone blockers, resulting in an endometrium which does not allow for implantation.

Progesterone blockers are very effective in inducing abortion… Ella is equipotent with RU-486 and is a derivative of RR-486, so we would reasonably expect that at equal doses Ella would abort implanted embryos. Further evidence of this is the very high efficacy of Ella when taken at any time during the cycle. This embryocidal activity resulted in the European Medicines Agency (EMEA) statement that ulipristal can cause the death of embryos.

What this means for women who take Ella is that the dose of Ella sold as "emergency contraception" is capable of producing enough progesterone blockade to kill an early embryo who has already implanted. This dose is also sufficient to prevent the embryo from implanting.

As stated, some embryocidal drugs have been labeled as contraceptives. For truly informed consent, it is important that women have the opportunity to discuss with their doctor the implications of the contraceptive method they choose, including those outlined above. The proposed rule removes this opportunity for a completely informed discussion with patients as to the effects of these drugs, and also stamps as endorsed the methods and implications by which they work, including their embryocidal effects.

Advancing harmful trends in American healthcare

Currently, American women face widespread reproductive health challenges that remain woefully underdiagnosed and undertreated. While family planning is a significant issue for many women, it is far from the only issue that impacts their health. Women deserve excellent healthcare and removing their ability to have personalized care from a qualified physician or other medical professional is not advancing their health – it is damaging it. Also, these drugs can have significant side effects of their own, including increased risk of potentially fatal blood clots (venous thromboembolism), hypertension, or stroke. Removing the prescription requirement for hormonal contraceptives does not help women – it lessens the level of medical care they receive.

Additionally, minors having over the counter access to contraception robs them of many things – screening for sexually transmitted infections, screening for sexual abuse or coercion, and counseling on safer sexual practices or abstinence.

Additionally, research should be supported into women's reproductive conditions to promote the development of evidence-based methods for treating them. There will be little

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motivation for this if hormonal contraceptives, available OTC, are seen as a panacea solution for women.

Underlying this whole conversation, AAPLOG has significant concerns with the delegated authority of the Health Resources and Services Administration (HRSA). It is known that HRSA has delegated authority regarding rules governing the contraception coverage mandates to individuals with strong ties to the abortion industry and pro-abortion advocacy, including to a committee assembled by the American College of Obstetricians and Gynecologists (ACOG). This is surely biased and contributes to the disregard of the dangerous impact these drugs have on preborn children in the earliest stages of development.

As to the future, this proposed rule is described as a first step in the larger move away from prescription requirements in the future of other ACA-mandated preventive services. This statement is concerning for the many reasons outlined above and as applies to any doctor practicing in any specialty.

AAPLOG is opposed to this proposed rule change in both theory and practice. Do not further remove us from the doctor-patient relationship by finalizing this rule; rather, allow us to continue providing excellent, evidence-based care to women.

Respectfully submitted,

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