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Women's Preventive Services Guidelines

Guideline Development

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine & (IOM), now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, the Health Resources and Services Administration (HRSA) awarded a five-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM Clinical Practice Guidelines We Can Trust. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

The purpose of the Women's Preventive Services Guidelines is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice. The Women's Preventive Services Initiative will review the recommendations biennially, or upon the availability of new evidence. Topics for future consideration can also be submitted on a rolling basis at the Women's Preventive Services Initiative website d.

Under section 2713 of the Public Health Services Act, non-grandfathered group health plans and issuers of nongrandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose.

Updated HRSA-Supported Women's Preventive Services Guidelines

HRSA is supporting the Women's Preventive Services Initiative clinical recommendations listed below for preventive services that address health needs specific to women and fill gaps in existing guidelines.*

Screening for Anxiety

The Women's Preventive Services Initiative recommends screening for anxiety in adolescent and adult women, including those who are pregnant or postpartum. Optimal screening intervals are unknown and clinical judgement should be used to

determine screening frequency. Given the high prevalence of anxiety disorders, lack of recognition in clinical practice, and multiple problems associated with untreated anxiety, clinicians should consider screening women who have not been recently screened.

Breast Cancer Screening for Average-Risk Women

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Breastfeeding Services and Supplies

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and the postpartum period to ensure the successful initiation and maintenance of breastfeeding.

Screening for Cervical Cancer

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Contraception**, ***

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Screening for Gestational Diabetes Mellitus

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100- g oral glucose tolerance test if results on the initial oral

glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Screening for Human Immunodeficiency Virus Infection

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Screening for Interpersonal and Domestic Violence

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Counseling for Sexually Transmitted Infections

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Well-Woman Preventive Visits

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services, including preconception, and many services necessary for prenatal and interconception care are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

Screening for Urinary Incontinence

The Women's Preventive Services Initiative recommends screening women for urinary incontinence annually. Screening should ideally assess whether women experience urinary incontinence and whether it impacts their activities and quality of life. The Women's Preventive Services Initiative recommends referring women for further evaluation and treatment if indicated.

The Women's Preventive Services Initiative recommends screening women for urinary incontinence as a preventive service. Factors associated with an increased risk for urinary incontinence include increasing parity, advancing age, and obesity; however, these factors should not be used to limit screening.

Several screening tools demonstrate fair to high accuracy in identifying urinary incontinence in women. Although minimum screening intervals are unknown, given the prevalence of urinary incontinence, the fact that many women do not volunteer symptoms, and the multiple, frequently-changing risk factors associated with incontinence, it is reasonable to conduct annually.

Screening for Diabetes Mellitus after Pregnancy

The Women's Preventive Services Initiative recommends women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum.

Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (eg, oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first 6 months postpartum regardless of the result.

Implementation Considerations

While not included as part of the HRSA-supported guidelines, the Women's Preventive Services Initiative also developed implementation considerations, available at http://www.womenspreventivehealth.org/ &, which provide additional clarity on implementation of the guidelines into clinical practice. The implementation considerations are separate from the clinical recommendations, are informational, and are not part of the formal action by the Administrator under Section 2713.

* Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 20, 2017. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the 2011 guidelines.

**(I)(a) Objecting entities—religious beliefs.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
 (i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (I)(a)(2) of this note. Such non-governmental plan sponsors include, but are not limited to, the following entities:

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order;

(B) A nonprofit organization;

(C) A closely held for-profit entity;

(D) A for-profit entity that is not closely held; or

(E) Any other non-governmental employer;

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (I)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in

paragraph (I)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (I)(a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (I)(a) will apply to the extent that an entity described in paragraph (I)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.
(b) Objecting individuals—religious beliefs. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (I)(b), and nothing in 45 CFR 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(II)(a) Objecting entities—moral convictions.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (II)(a)(2) of this note:
(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934); (ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (II)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (II)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (II)(a)(1)(iii), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (II)(a) will apply to the extent that an entity described in paragraph (II)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) Objecting individuals—moral convictions. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (II)(b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(III) Definition. For the purposes of this note, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified

for purposes of these Guidelines.

See Federal Register Notice: <u>Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under</u> <u>the Affordable Care Act</u> (PDF - 488 kb).

***General Notice

As a result of court decisions, the final rules (83 FR 57536 (Nov. 15, 2018); 83 FR 57592 (Nov. 15, 2018)) and the interim final rules (82 FR 47792 (Oct. 13, 2017); 82 FR 47838 (Oct. 13, 2017)) regarding exemptions for certain plans and issuers from covering certain contraceptive items and services based on religious and moral objections are not in effect. See Pennsylvania v. Trump, 351 F. Supp. 3d 791 (E.D. Pa. 2019), aff'd 930 F. Supp. 3d 543 (3d Cir. 2019); see also California v. Azar, 351 F. Supp. 3d 1267 (N.D. Cal. 2019) (enjoining the final rules with respect to plaintiff states).

On July 29, 2019, in a case in the Northern District of Texas, DeOtte v. Azar, No. 4:18-CV-00825-O, 2019 WL 3786545 (N.D. Tex. July 29, 2019) the court determined that the "Contraceptive Mandate, codified at 42 U.S.C. § 300gg–13(a)(4), 45 C.F.R. § 147.130(a)(1)(iv), 29 C.F.R. § 2590.715–2713(a)(1)(iv), and 26 C.F.R. § 54.9815–2713(a)(1)(iv), violates the Religious Freedom Restoration Act" with respect to individuals and entities with religious objections to contraceptive coverage and thus enjoined enforcement of those provisions against such individuals and entities.

The Departments of Labor, Health and Human Services, and the Treasury are working with the Department of Justice in these on-going suits.

Date Last Reviewed: December 2019

Learn More

- Women's Preventive Services Initiative report Image: March 1998
- 2011 IOM Report Clinical Preventive Services for Women: Closing the Gaps
- 2016 Guidelines
- <u>US Preventive Services Task Force</u>
- Bright Futures
- Advisory Committee on Immunization Practices Press



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