• WREN Laboratories LLC's WREN Laboratories COVID–19 Saliva Test Collection Kit DTC, issued June 17, 2021; [9]

• Tidal Medical Technologies LLC's InSee incentive spirometer accessory, issued June 30, 2021; [10]

• Everlywell, Inc.'s Everlywell COVID–19 & Flu Test Home Collection Kit, issued July 1, 2021; [11]

• Becton, Dickinson and Company's BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site), issued July 22, 2021; [12]

• Kwokman Diagnostics, LLC's Kwokman Diagnostics COVID–19 Home Collection Kit, issued August 13, 2021; [13] and

• Yale School of Public Health, Department of Epidemiology of Microbial Diseases' SalivaDirect DTC Saliva Collection Kit, issued August 27, 2021.[14]

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23501 Filed 10–27–21; 8:45 am]

BILLING CODE 4164–01–P

[9] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC may be effective in diagnosing COVID–19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC when used for such use, outweigh the known and potential risks of the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC; and (3) there is no adequate, approved, and available alternative to the emergency use of the WREN Laboratories COVID–19 Saliva Test Collection Kit DTC.

[10] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the InSee COVID–19 may be effective in treating respiratory conditions in patients with COVID–19 in hospital settings by quantitatively tracking patient usage of Vyaire Medical's AirLife incentive spirometer, and that the known and potential benefits of the InSee when used for treating COVID–19, outweigh the known and potential risks of InSee; and (3) there is no adequate, approved, and available alternative to the emergency use of the InSee for treating COVID–19 for such use.

[11] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Everlywell COVID–19 & Flu Test Home Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 influenza A and/or influenza B nucleic acids from the home collected human specimen and that the known and potential benefits of the Everlywell COVID–19 & Flu Test Home Collection Kit when used for diagnosing COVID–19, outweigh the known and potential risks of the Everlywell COVID–19 & Flu Test Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the Everlywell COVID–19 & Flu Test Home Collection Kit.

[12] FDA is using the term ''UK Manufacturing Site'' to differentiate the authorized version from the FDA-cleared version of these products that are also manufactured by Becton, Dickinson and Company. As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) may be effective in aiding in the identification and treatment of coagulopathy in patients, including patients with known or suspected COVID–19, by collecting, transporting, and storing blood specimens for coagulation testing, and that the known and potential benefits of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site) when used for such use, outweigh the known and potential risks of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site); and (3) there is no adequate, approved, and available alternative to the emergency use of the BD Vacutainer Plus Citrate Plasma Tubes (UK Manufacturing Site).

[13] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Kwokman Diagnostics COVID–19 Home Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the home-collected human specimen, and that the known and potential benefits of the Kwokman Diagnostics COVID–19 Home Collection Kit when used for such use, outweigh the known and potential risks of the Kwokman Diagnostics COVID–19 Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the Kwokman Diagnostics COVID–19 Home Collection Kit.

[14] As set forth in the EUA, FDA has concluded that: (1) SARS–CoV–2, the virus that causes COVID–19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus; (2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the SalivaDirect DTC Saliva Collection Kit may be effective in diagnosing COVID–19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS–CoV–2 RNA from the self-collected human specimen, and that the known and potential benefits of the SalivaDirect DTC Saliva Collection Kit when used for such use, outweigh the known and potential risks of the SalivaDirect DTC Saliva Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the SalivaDirect DTC Saliva Collection Kit.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updated HRSA-Supported Women's Preventive Services Guidelines: Contraception and Screening for HIV Infection

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice seeks comments on two updated draft recommendations for (1) providing contraception and (2) screening for human immunodeficiency virus (HIV) infection, as part of the HRSA-supported Women's Preventive Services Guidelines (Guidelines). These updated draft recommendations have been developed through a national cooperative agreement, the Women's Preventive Services Initiative (WPSI), by the American College of Obstetricians and Gynecologists (ACOG). Under applicable law, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported Women's Preventive Services Guidelines (Guidelines). The Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury have previously issued regulations, which describe how group health plans and health insurance issuers apply the coverage requirements, including the use of reasonable medical management. (*See* 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130).

DATES: Members of the public are invited to provide written comments no later than November 29, 2021. All comments received on or before this date will be reviewed and considered by the WPSI Multidisciplinary Steering Committee.

ADDRESSES: Members of the public interested in providing comments on the draft recommendation statements can do so by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone (301) 443–8283, email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: As provided for in section 1001(5) of the

Patient Protection and Affordable Care Act, Public Law 111–148, which added section 2713 to the Public Health Service Act, 42 U.S.C. 300gg–13, HRSA established the Guidelines in 2011 based on a study and recommendations by the Institute of Medicine, now known as the National Academy of Medicine, developed under a contract with the Department of Health and Human Services. Since then, there have been advancements in science and gaps identified in these guidelines, including a greater emphasis on practice-based clinical considerations. In March 2016, HRSA awarded a 5-year cooperative agreement to the ACOG to convene a coalition representing clinicians, academics, and consumer-focused health professional organizations to conduct a rigorous review of current scientific evidence and make recommendations to HRSA regarding updates to the existing Guidelines. HRSA awarded ACOG the cooperative agreement to improve adult women's health across the lifespan by engaging a coalition of health professional organizations to review evidence and recommend updates to the HRSA-supported Guidelines. HRSA would then decide whether to support, in whole or in part, the recommended updates to the Guidelines. Under the cooperative agreement, ACOG formed WPSI, consisting of an Advisory Panel and two expert committees, the Multidisciplinary Steering Committee (MSC) and the Dissemination and Implementation Steering Committee (DISC), which are comprised of a broad coalition of organizational representatives who are experts in disease prevention and women's health issues. Through oversight by the Advisory Panel, MSC and DISC support the development and implementation of the Guidelines through the review of existing evidence and recommendation development. Specifically, the MSC examines the evidence to develop new and update existing recommendations for women's preventive services. DISC takes the HRSA-approved recommendations, developed by the MSC, and works to disseminate the recommendations through the development of implementation tools and resources for both patients and practitioners to support the adoption and utilization of the recommendations.

In March 2021, HRSA awarded a subsequent cooperative agreement to ACOG to further review and recommend updates to the Guidelines. Under this cooperative agreement, beginning on March 1, 2021, ACOG engaged in a process to consider and review new information. Following recommendations by ACOG, HRSA will decide whether to support, in whole or in part, its recommended updates to the guidelines.

Under the cooperative agreement, ACOG will base its recommended updates to the Guidelines on review and synthesis of existing clinical guidelines and new scientific evidence, following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, as well as external reviews. Additionally, ACOG will incorporate processes to assure opportunity for public comment, including participation by patients and consumers, in the development of the updated Guideline recommendations.

This notice solicits comments from the public on draft recommendations for providing contraception and screening for HIV infection. The updated draft recommendations are provided below. WPSI will consider and, as necessary, incorporate public comment. HRSA will then decide whether to support, in whole or in part, the recommended updates to the guidelines.

Contraception

ACOG, through the WPSI/MSC, made updates to the clinical recommendation statement to clarify the terminology from contraceptive methods to contraceptives. The Committee has also removed the term ''female-controlled contraceptives'' to allow women to purchase male condoms for pregnancy prevention. Lastly, the Committee has further defined the existing components of contraceptive follow-up care to include the management and evaluation of and changes to—including the removal, continuation, and discontinuation of—the contraceptive.

''The Women's Preventive Services Initiative recommends adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve health outcomes. Contraceptive care includes screening, counseling, education, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (*e.g.,* management and evaluation of and changes to, including, removal, continuation, discontinuation of, the contraceptive method).

The Women's Preventive Services Initiative recommends the full range of U.S. Food and Drug Administration (FDA) approved contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods currently identified by FDA include: (1) Sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), (7) oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel); and (17) emergency contraception (ulipristal acetate); additional methods as identified by the FDA.''

Screening for HIV Infection

ACOG, through the WPSI/MSC, has recommended minor updates to the screening for HIV infection recommendation statement to specify that screening should begin at age 15 and older, and that earlier detection should be based on a review of patient risk factors.

''The Women's Preventive Services Initiative recommends all women, ages 15 and older, receive a screening test for HIV at least once during their lifetime. Earlier or additional screening should be based on risk, and re-screening annually or more often may be appropriate beginning at age 13 for adolescents and women with an increased risk of HIV infection.

The Women's Preventive Services Initiative recommends risk assessment and prevention education for human immunodeficiency virus (HIV) infection beginning at age 13 and continuing at least annually throughout the lifespan as determined by risk. A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in labor with an undocumented HIV status.''

Members of the public can view each complete updated draft recommendation statement by accessing the initiative's web page at *https://www.womenspreventivehealth.org/.*

Diana Espinosa,

Acting Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.