



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Notice of Request for Comments on Draft Recommendations to Update the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Cervical Cancer**

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

**ACTION:** Notice

**SUMMARY:** This notice seeks comment on draft recommendations for the HRSA-supported Women's Preventive Services Guidelines (Guidelines) relating to Screening for Cervical Cancer. Under applicable law, non-grandfathered group health plans and health insurance issuers must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported Guidelines. The Departments of Labor, Health and Human Services, and Treasury have issued regulations and policy guidance which describe how group health plans and health insurance issuers apply the coverage requirements.

**DATES:** Members of the public are invited to provide written comments no later than [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. All comments received on or before this date will be reviewed and considered by HRSA in determining the recommended updates that it will support.

**ADDRESSES:** Public comments must be submitted electronically to HRSA at [wellwomancare@hrsa.gov](mailto:wellwomancare@hrsa.gov).

**FOR FURTHER INFORMATION CONTACT:** Kimberly Sherman, HRSA, Maternal and Child Health Bureau, at (301) 443-8283 or [wellwomancare@hrsa.gov](mailto:wellwomancare@hrsa.gov).

**SUPPLEMENTARY INFORMATION:** Under section 1001(5) of the Patient Protection and Affordable Care Act, Public Law 111-148 (<https://www.govinfo.gov/link/plaw/111/public/148>), which added section 2713 to the Public Health Service Act, 42 U.S.C. 300gg-13 (<https://www.govinfo.gov/link/uscode/42/300gg-13>), the preventive care and screenings set forth in the HRSA-Supported Women's Preventive Services Guidelines are required to be covered without cost-sharing by certain group health plans and health insurance issuers. HRSA established the initial Guidelines in 2011.

Since 2016, HRSA has funded cooperative agreements to support the Women's Preventive Services Initiative (WPSI) to convene clinicians, academics, and consumer-focused health professional organizations who are experts in disease prevention and women's health issues to conduct a rigorous review of current scientific evidence and make recommendations to HRSA regarding updates to the Guidelines to improve women's health across the lifespan. After public comment is solicited and considered, HRSA determines whether to support, in whole or in part, the recommended updates to the Guidelines.

Recommended updates to the Guidelines are based on review and synthesis of existing clinical guidelines and new scientific evidence, following robust standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, and external reviews. Additionally, HRSA requires incorporation of processes to assure opportunity for public comment, including participation by patients and consumers, in the development of its recommendations to update the Guidelines. This notice seeks comment on one draft Guideline:

### **Screening for Cervical Cancer**

The current Guideline for Screening for Cervical Cancer is: "WPSI 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. Co-testing 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.”

The proposed updated Guideline for Screening for Cervical Cancer is: “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, cervical cancer screening using cervical cytology (Pap test) every 3 years is recommended. Co-testing with cytology and human papillomavirus (hrHPV) testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with primary hrHPV testing every 5 years (preferred) or cytology and hrHPV testing (co-testing) every 5 years. If hrHPV testing is not available, continue screening with cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years. Patient-collected hrHPV testing is an appropriate method and should be offered as an option for cervical cancer screening in women aged 30 to 65 years at average risk. Additional testing may be required to complete the screening process and follow-up findings on the initial screening. If additional testing (e.g., cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation are indicated, these services also are recommended to complete the screening process for malignancies.”

**BACKGROUND:** WPSI recommends several updates to the language of this Guideline. The first change is the use of the full form of WPSI in the first sentence of the Guideline. The second change occurs in the second sentence of the Guideline and only restructures the sentence for clarity and does not provide any changes to the recommendation. Next, there was a recommendation to add the abbreviation “hrHPV” after the term “human papillomavirus” for consistency and increased clarity that the recommendation is specific to high-risk HPV types. Corresponding revisions utilizing the abbreviation are provided throughout the remaining text of the updated recommendation. WPSI also recommends updates to the Guideline regarding cervical cancer testing for women aged 30-65 and added “primary hrHPV testing every 5 years (preferred) or cytology and hrHPV testing (co-testing) every 5 years. If hrHPV testing is not

available, continue screening with cytology alone every 3 years.” This update reflects current evidence-based practice on testing and interval screening. Next, a new sentence was added (“Patient-collected hrHPV testing is an appropriate method and should be offered as an option for cervical cancer screening in women aged 30 to 65 years at average risk.”) to reflect the new evidence and developments supporting the expansion of options for cervical cancer screening through patient-collected hrHPV testing. The last update to the Guideline adds a sentence on the necessity of additional testing to complete the cervical cancer screening process (“If additional testing (e.g., cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation are indicated, these services also are recommended to complete the screening process for malignancies.”). This update ensures the screening process for malignancies is complete should additional testing services (e.g., cytology, biopsy colposcopy, extended genotyping, dual stain) and pathologic evaluation be clinically indicated. Additional testing to complete the screening process covers all cases of cervical cancer screening, regardless if the test was collected by the patient or clinician.

Comments are sought on these proposed updates. Members of the public can view the complete updated draft clinical recommendation, evidence review, as well as the implementation considerations and research recommendations (which are not part of the Guidelines), by accessing <https://www.hrsa.gov/womens-guidelines>.

**Thomas J. Engels,**

*Administrator.*