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Submitted electronically: wellwomancare@hrsa.gov.

Re: Notice of Request for Comments on Draft Recommendations to Update the HRSA-Supported Women's Preventive Services Guidelines Relating to Screening for Cervical Cancer (FR Doc. 2025-19186)

Dear Ms. Sherman,

The Society of Gynecologic Oncology (SGO) appreciates the opportunity to review and provide comments on the Health Resources and Services Administration (HRSA) Public Comment on Women's Preventive Services Guidelines Relating to Screening for Cervical Cancer.

The SGO is the premier medical specialty society for healthcare professionals trained in the comprehensive management of gynecologic cancers. Our 3,000+ members include physicians, advanced practice providers, nurses, and patient advocates who collaborate with the SGO's foundation, the Foundation for Women's Cancer, to increase awareness of gynecologic cancers and improve the care of those diagnosed with gynecologic cancers. Our mission focuses on supporting research, disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations dedicated to gynecologic cancers and related fields, all with the ultimate vision of eradicating gynecologic cancers.

We respectfully submit the following comment.

Background and Ongoing Gaps in Coverage:

Under the Affordable Care Act (ACA), Medicare, Medicaid, and private health plans are required to cover evidence-based preventive services without patient cost-sharing.

However, patients often incur cost-sharing for follow-up diagnostic procedures such as colposcopy after an abnormal Pap test or positive human papillomavirus (HPV) test and other related services. Despite the availability of the HPV vaccine (primary prevention) and screening tests (secondary prevention), the decreases in incidence of and mortality from cervical cancer has plateaued in the United States.^{1,2,3} This is unacceptable since advances in testing and treatment should be moving us closer to elimination of cervical cancer. Unfortunately, the positive effects of screening are negated when there are barriers to follow-up testing to evaluate abnormal screening results, and to treatment for individuals with precancerous lesions. High out-of-pocket costs for follow-up testing and treatment continue to prevent or delay completion of the screening and prevention process, a barrier well-documented in the literature. This results in delayed treatment⁴ of precancerous lesions and ultimately limits our country's ability to effectively prevent cervical cancer, particularly in underinsured women.

Updates and Coverage Clarification Needed:

SGO supports the HRSA Women's Preventive Services Initiative (WPSI) proposed update to expand and modernize cervical cancer screening by elevating primary high-risk HPV (hrHPV) as the preferred screening method for women ages 30 to 65, and by explicitly including patient-collected hrHPV testing as an option to improve access. WPSI appropriately states that "patient-collected hrHPV testing is an appropriate method and should be offered as an option for cervical cancer screening in average-risk women aged 30 to 65 years." SGO recommends clarifying that this option be treated as a covered preventive service now, even with current FDA limitations and pending completion of the NCI's ongoing Last Mile Initiative⁵. HRSA's recommendation should not be constrained by regulatory timing; if WPSI endorses self-collection, insurers must be required to cover it, which includes an HPV test

¹ National Cancer Institute, SEER Program. (n.d.). *Cancer Stat Facts: Cervical Cancer*. Retrieved October 24, 2025, from [Cervical Cancer — Cancer Stat Facts](#)

² Yang DX, Soulos PR, Davis B, Gross CP, Yu JB. Impact of Widespread Cervical Cancer Screening: Number of Cancers Prevented and Changes in Race-specific Incidence. *Am J Clin Oncol*. 2018 Mar;41(3):289-294. doi: 10.1097/COC.000000000000264. PMID: 26808257; PMCID: PMC4958036.

³ American Cancer Society. (2025, July 1). *Key statistics for cervical cancer*. Retrieved October 24, 2025, from [Cervical Cancer Statistics | Key Facts About Cervical Cancer | American Cancer Society](#)

⁴ Harper DM, Yu TM, Fendrick AM. Lives Saved Through Increasing Adherence to Follow-Up After Abnormal Cervical Cancer Screening Results. *O G Open*. 2024 Mar 19;1(1): e001. doi: 10.1097/og9.0000000000000001. PMID: 38533459; PMCID: PMC10964775.

⁵ National Cancer Institute. (n.d.). "NCI Cervical Cancer 'Last Mile' Initiative". Retrieved October 24, 2025, from <https://prevention.cancer.gov/research-areas/networks-consortia-programs/last-mile>

without a Pap, regardless of current labeling status. Expanded access is essential to reducing cervical cancer rates.

Preventive Follow-Up Services Must Be Explicitly Protected

SGO appreciates the acknowledgement that additional testing and pathological evaluation beyond the initial Pap and/or hrHPV tests are integral components of the cancer screening process. While cervical cancer is preventable through regular screening, and cervical cancer detected at early stages is often curable, coverage for cervical cancer screening alone is only part of the screening process. Our concerns with the proposed guidance are twofold.

Clarify that all follow-up services are preventive, not diagnostic.

SGO believes that the proposed language is not broad enough to ensure access to the full spectrum of available cervical cancer screening tests and self-sampling. When guidelines use language like “may be required” or “is recommended” without stating that follow-up testing remains an integral part of the preventive screening process, it leaves intact the long-standing “screening vs diagnostic” loophole used by insurers to impose cost-sharing policies. In practice, this language then results in the necessary follow-up procedures being treated as diagnostic rather than preventive, placing those tests outside the ACA’s requirement to eliminate cost-sharing. This leads to coverage denials or high out-of-pocket costs for patients. Guidance language must be explicit and firmly state that all necessary follow-up testing services are part of preventive screening and are not diagnostic in nature.

Implementation Requires Funding

SGO recognizes that funding decisions fall outside WPSI’s direct authority. However, its language directly influences whether follow-up services qualify as preventive services under the ACA^{6,7}. If they are not clearly defined as preventive within the guideline, access barriers, including cost-sharing, will persist despite the intent of the recommendation.

⁶ *The ACA Preventive Services Coverage Requirement*. (2025, October 24). <https://www.congress.gov/crs-product/IF13010>

⁷ U.S. Department of Health & Human Services, Health Resources & Services Administration. (2025, September). *Women’s Preventive Services Guidelines*. Retrieved October 24, 2025, from [Women’s Preventive Services Guidelines | HRSA](#)

Recommendations

To ensure the intent of the guidance is fully realized in practice, SGO recommends that WPSI:

- Explicitly define all necessary follow-up procedures that are clinically required as part of the preventive screening process for malignancies and are not diagnostic since this is what ensures ACA zero-cost-sharing coverage and real-world patient access.
- Make clear that patient-collected hrHPV testing must be covered as a preventive service now, without a Pap test, even though FDA approval is currently limited to supervised, in-clinic collection and the NCI's Last Mile Initiative is ongoing.

Thank you for the opportunity to provide comments on the HRSA- WPSI draft recommendations relating to screening for cervical cancer. If you have questions or need additional information, please contact Carly Leon, Manager, Health Policy and Government Affairs: carly.leon@sgo.org.

Thank you,



Karen H. Lu, MD
President, Society of Gynecologic Oncology