POINT OF CARE TESTING ASSOCIATION

September 8, 2025

VIA Electronic Submission to www.regulations.gov

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; CMS–1832–P

Dear Dr. Oz:

On behalf of the Point of Care Testing Association (POCTA),[1] we are pleased to provide the following comments responding to proposals and other policy discussions included within CMS's Medicare Physician Fee Schedule (MPFS) proposed update for CY 2026. For the reasons outlined below, we respectfully request that CMS:

1. Proceed to establish and implement payment policies that encourage development of **Urgent Care Centers** to provide beneficiaries with more and more appropriate points of access for urgent, non-emergent care; and

2. Confirm that CMS will pay separately for vaginal specimen self-collection devices (e.g., for HPV screening or vaginitis testing) in both the physician office and hospital outpatient settings.

3. Maintain current Medicare Clinical Lab Fee Schedule (CLFS) rates and adjust the future data collection and reporting periods.

[1] POCTA seeks to facilitate access to safe, effective, and cost-effective patient testing at the time of treatment. Laboratory testing furnished at the point of care (POC) benefits patients and the health care system. POC testing enables physicians to monitor chronic conditions, diagnose illnesses, and provide timely information to patients in a variety of care settings, from clinics to pharmacies to community centers to non-hospital facilities (e.g., assisted living). POCTA works to develop reimbursement policies that can improve health outcomes by supporting access to POC testing. POCTA is comprised of Abbott Rapid Dx, Abbott Point of Care, Beckman Coulter Diagnostics, Becton, Dickinson and Company (BD), Cepheid, Roche Diagnostics Corporation, and Sekisui.

I. Request for CMS to establish and implement payment policies that encourage development of Urgent Care Centers to provide beneficiaries with more and more appropriate points of access for urgent, non-emergent care

In the CY 2025 PFS proposed rule, CMS sought public comment on how urgent care centers could serve as an appropriate setting to treat patients with non-emergent urgent care needs and could play a role in addressing some of the capacity issues in emergency departments (EDs). In this rule, CMS follows up on that comment solicitation by seeking input on whether separate coding and payment is needed for evaluation and management (E/M) visits furnished at urgent care centers— especially "enhanced" urgent care centers that offer specific diagnostic and therapeutic services and operate outside typical business hours. POCTA is pleased that CMS continues to be interested in exploring ways to improve system capacity and workforce issues broadly, and that CMS is specifically looking at how urgent care centers can help address these challenges. POCTA member companies supply point of care laboratory diagnostics capabilities to urgent care centers around the country, and our organizations know intimately how urgent care centers, particularly those with point of care laboratory diagnostics capabilities, effectively and efficiently support patients with urgent, but non-emergent care needs.

POCTA believes that CMS should create payment policies that incentivize the proliferation of enhanced urgent care centers, including the adoption of a new add-on code to more assertively address system capacity and workforce issues. Enhanced urgent care centers can help provide Medicare beneficiaries with timely access to clinician services and point of care testing for urgent but non-emergent needs in settings outside of both EDs and physician offices. By bridging the gap between these settings, enhanced urgent care centers can alleviate system capacity constraints, reduce avoidable ED visits, and offer a cost-effective alternative for patients who require same-day attention. More access to these entities also would help ensure that more beneficiaries gain access to diagnostics and laboratory testing at the time of treatment and receive more timely and actionable results— results that improve patient experience, begin treatment faster, more aggressively halt infectious disease, and save the health system resources.

As CMS references, services delivered in enhanced urgent care centers are paid at the same rate as services provided in other non-facility settings. The current set of E/M codes do not fully capture the additional complexity of the clinical work inherent in enhanced urgent care center visits. These encounters involve unique and often greater cognitive demands: clinicians must evaluate and treat urgent but non-emergent conditions in compressed time frames and with incomplete medical histories, establish rapport and trust quickly, synthesize evolving information, order and interpret diagnostics, and initiate treatment plans, which sometimes includes escalation to a higher-level of care. An add-on code would allow CMS to recognize the additional cognitive effort and higher practice expense associated with enhanced urgent care center E/M visits without overhauling the

E/M code structure or creating a standalone code set, which could take significant time with no assurance that the final outcome would resolve the underlying payment misalignment. POCTA encourages CMS to move forward with payment policy changes to enhance the proliferation of enhanced urgent care centers, and to do so as expeditiously as is reasonable.

II. Request for CMS to Confirm Medicare Will Pay Separately for Vaginal Specimen Self-Collection Devices (e.g., For HPV Screening Or Vaginitis Testing) in Both the Physician Office and Hospital Outpatient Settings

USPSTF recommends screening women aged 30-65 for cervical cancer every 3 years with cervical cytology alone, every 5 years with high-risk papillomavirus testing (HPV) testing alone, or every 5 years with HPV testing in combination with cytology (cotesting).[2] However, just 70-80% of eligible individuals are up-to-date with recommended screening.[3] Clinicians diagnose half of all new cases of cervical cancer in patients who were not screened or inadequately screened as recommended by current guidelines.[4]

Similarly, the use of multiplex nucleic acid amplification tests (NAATs) for detection of organisms associated with bacterial vaginosis is supported in updated IDSA/American Society for Microbiology guidelines.[5] However, the rate of undiagnosed vaginitis in symptomatic patients is as high as 72%.[6] Misdiagnosis (or delayed diagnosis) may lead to unnecessary, delayed, or inadequate treatment and cause harm to patients, such as avoidable return visits to the provider, inappropriate prescriptions, increased susceptibility to sexually transmitted infections or human immunodeficiency virus.

Until recently, these tests required a health care professional to collect the specimen during a pelvic examination. This procedure is invasive and causes many otherwise eligible women to skip recommended testing, for reasons such as socioeconomic barriers, history of traumatic experience, mobility issues, and/or embarrassment. The U.S. Food and Drug Administration (FDA) has approved multiple tests that allow patients to self-collect vaginal

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[2] United States Preventive Services Task Force, Cervical Cancer: Screening (August 2018), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening.
[3] Spencer JC, Kim JJ, Tiro JA, et al. Racial and ethnic disparities in cervical cancer screening from three U.S. healthcare settings. Am J Prevent Med 2023;65(4):667-677.
[4] National Cancer Institute, FDA approves HPV tests that allow for self-collection in a health care setting (July 24, 2024), https://www.cancer.gov/news-events/cancer-currents-blog/2024/fda-hpv-test-self-collection-health-care-setting.
[5] Miller JM et al. Guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2024 update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). Clin Infect Dis 2024, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciae104/7619499?login=false.
[6] Brown H, Drexler M. Improving the diagnosis of vulvovaginitis: perspectives to align practice, guidelines and awareness. Popul Health Manag 2020;16(23 Suppl 1):S3-S12.

samples, which are then sent to a laboratory for accurate, reliable HPV or vaginitis testing..And in February of this year, the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee of the American Society for Colposcopy and Cervical Pathology (ASCCP) released guidelines supporting self-collected HPV testing. ASCCP endorsed the USPSTF cervical cancer screening guidelines, and define self-collected vaginal samples as "acceptable for primary HPV screening of asymptomatic average-risk individuals" with "repeat testing in 3 years" after a negative HPV primary test when using self-collected samples.

The addition of a self-collection option promises to substantially improve patient access to recommended procedures by removing meaningful barriers associated with previous collection methods. For example, Ogale *et al*. report that testing programs offering self-collection of samples increased overall uptake of STI testing services (RR: 2.941, 95% CI 1.188 to 7.281) and case finding (RR: 2.166, 95% CI 1.043 to 4.498).[7]

Medicare currently covers HPV screening performed with an FDA-approved or FDA-cleared kit—including on self-collected vaginal specimens—when furnished in conjunction with Pap smear for asymptomatic patients 30-65 years old,[8] as well as the cost of the cost of obtaining other types of specimens for cervical cancer screening.[9] (Separately, we understand Medicare has received a request to expand coverage for stand-alone HPV testing to track with current USPSTF recommendations.) Medicare also currently covers diagnostic laboratory testing for vaginitis.[10]

Medicare does not, however, cover any costs incurred by a physician office or hospital outpatient department when purchasing and furnishing self-collection kits to patients. The acquisition cost of these collection kits to clinician practices places a meaningful financial burden on clinician offices. As a result, Medicare payment policy currently leaves physicians with a financial disincentive to offer this clinically validated, FDA approved collection option that may substantially improve patient adherence to recommended screening guidelines.

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[7] Ogale Y, Yeh PT, Kennedy CE, *et al*. Self-collection of samples as an additional approach to deliver testing services for sexually transmitted infections: a systematic review and meta-analysis. *BMJ Glob Health* 2019;4(2):e001349.

[8] *See* National Coverage Determination: Screening for Cervical Cancer with Human Papillomavirus (HPV) (NCD 210.2.1), https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=365.

[9] E.g., a pap smear, reported with HCPCS code Q0091

[10] *See* MolDx: Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing (L38988), https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38988.

Proposed Solution

To ensure Medicare beneficiaries are offered the same flexibilities and access as patients with other insurance, **we encourage CMS to:**

(1) Confirm that Medicare will pay separately for the cost of a vaginal specimen self-collection kit (assign OPPS status indicator "A" or "V", MPFS status indicator "A"); and

(2) Create a new HCPCS code that will be appropriate to report the provision of the self-collection kit to patients for use in the hospital outpatient department or office setting.

Separate payment of vaginal specimen self-collection kits is appropriate as these kits meet all the criteria for "incident to" billing:[11]

"Incident to" requirement	**Met by physician provision of self-collection kit?**
Integral, although incidental, part of the physician's professional service?	**Yes –** professional society guidelines support the role of physicians in counseling patients to receive appropriate screening for cervical cancer[12] and/or testing for vaginitis
Commonly included in the patient's bill?	**Yes** – when the collection device represents an actual expense to the furnishing clinician, it would be appropriate for inclusion in the patient's bill
Of a type that is commonly furnished in physician's offices or clinics?	**Yes** – the collection devices are FDA-approved to obtain "self-collected vaginal specimens, obtained in a healthcare setting…"[13]
Furnished by the physician (or auxiliary personnel under the physician's direct supervision)	**Yes** – the physician (or the physician's staff, when the physician is physically present in the office and available to provide assistance) provides the self-sampling kit to the patient

During a recent meeting with CMS officials, the CMS team raised two questions regarding this specific proposal. In response, we offer the following comments for your consideration:

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[11] CMS, Medicare Benefit Policy Manual, chapter 13, section 60(A), https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.
[12] *See, e.g.,* American College of Obstetricians and Gynecologists (ACOG), Updated Cervical Cancer Screening Guidelines (April 2021), https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/04/updated-cervical-cancer-screening-guidelines.
[13] *See, e.g.,* https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190028S009A.pdf; https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160037S017A.pdf.

1. **Do patients typically receive self-collection kits in the physician office or hospital outpatient setting?** Given how recently the FDA authorized these self-collection kits, we have limited data on the number of encounters where patients receive these kits. However, we expect utilization to increase substantially in future years. For example, starting in Measurement Year 2024, the National Committee for Quality Assurance clarified that self-collected samples processed by a laboratory or provider's office may be used for reporting HEDIS measures.[14] Furthermore, two large laboratories recently announced they would begin testing self-collected specimens starting later this year.[15]

2. **Is the cost of the self-collection kits already captured in the payments for HPV and vaginitis testing?** Patients would most likely receive the self-collection kits during an evaluation and management (E/M) visit reported with CPT codes 99202-99215. Self-collections kits are not included as a supply in the practice expense inputs for these E/M codes; the only supplies included are the pack for the E/M visit, and a sanitizing cloth wipe. A potential new code for the specimen collection kit could be reported separately in addition to the underlying service code.

   Note – if the patient receives a Pap smear, self-collection would not be necessary. The cost of the supplies used in a pelvic exam are included in the MPFS practice expenses for the pelvic exam (reported with CPT code 99459).

III. Maintain current Medicare Clinical Lab Fee Schedule (CLFS) rates and adjust the future data collection and reporting periods.

CLFS Rates: Sec. 216 of the Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to base CLFS rates on commercial payor rates for laboratory services. As you know, under PAMA, laboratories are required to report their commercial payor rates and the associated volumes to CMS every three years. CMS then uses this data to develop a volume-weighted median for each test code on the CLFS.

Without any additional action by Congress or CMS, labs would experience another payment cut of up to 15 percent in 2026, and be required to report new commercial payor rate information if CMS proceeds with a data collection effort. While Congress has

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[14] *See* HEDIS MY 2024, Volume 2, Summary Table of Measures, Product Lines and Changes ("Updated General Guideline Member-Collected Samples to clarify that member-collected samples processed by a laboratory or provider's office may be used for reporting").
[15] *See* https://newsroom.questdiagnostics.com/2025-04-02-Quest-Diagnostics-Introduces-HPV-Specimen-Self-Collection-for-Cervical-Cancer-Screening; https://www.labcorp.com/education-events/press-releases/labcorp-offer-hpv-and-sti-self-collection-options-labcorp-patient-service-centers-and-participating.

prevented payment cuts through 2025, the law, as written, does not require congressional action to stave off these cuts, or require CMS to undertake a new data collection activity immediately. CMS has the discretion to prevent these cuts and set new data collection periods, and should exercise its discretion to do so.

The current data collection period is January 1 – June 30, 2019. Using data from five years ago will not result in appropriate rates. CMS should advance this period to January 1 – June 30, 2026.

CMS has previously used its authority to adjust the reporting periods. Should the agency adjust the data collection period as recommended above, CMS should also delay the data reporting period to January 1 – March 31, 2027, to allow laboratories time to adjust to the new requirements.

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Thank you for your consideration of our comments. If you have any questions or comments, please contact me at 202-756-8088 or via e-mail at mryan@mwe.com.

Sincerely,

Mike Ryan
On behalf of the Point of Care Testing Association