October 5, 2020

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies (CMS-1734-P)

Dear Administrator Verma:

On behalf of the American Society for Clinical Pathology (ASCP) and American Society of Cytopathology (ASC), we are writing to provide comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Physician Payment Schedule (PFS) for calendar year (CY) 2021, published in Federal Register on the August 17 (Vol. 85, Federal Register (FR), pages 50074-50665). This letter addresses our concerns with proposed changes to a cervical cancer screening measure outlined at Table D.63 that would abandon cervical cytology/human papillomavirus (HPV) co-testing.

Cervical Cancer Screening

In the proposed rule, CMS outlines a number of proposed changes to previously finalized quality measures (see TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2023 MIPS Payment Year and Future Years, pp, 85 FR 50632-50663). Included among these measures is one for cervical cancer screening (See 85 FR 50586, D.63 Cervical Cancer Screening), identified as eCQM measure CMS124v9.

CMS states that it is proposing to remove the Pap test component (and allowing only HPV testing every 5 years) in the second of the two criterion in the numerator. ***What CMS is proposing would eliminate the option for physicians to report on cervical cytology/HPV co-testing from the measure***. ASCP and ASC are strongly opposed to this proposal and believe that it could negatively impact patient care and increases the risk of death to women from cervical cancer.

As rationale, CMS states that it is proposing to "*update the measure to align with current clinical guidelines*, which removes the Pap test requirement and allow[s] HPV only testing every 5 years." This statement is erroneous. **There are numerous guidelines available pertaining to cervical cancer and *we are unaware of any that do not recognize the importance of cervical cytology/HPV co-testing in the cervical cancer screening algorithm***.

The U.S. Preventative Services Task Force (USPSTF) "For women aged 30 to 65 years, [it] recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk HPV (hrHPV) testing alone, ***or every 5 years with hrHPV testing in combination with cytology (Cotesting). Importantly, USPSTF gives this recommendation an "A" rating, meaning "there is high certainty that the net benefit is substantial [emphasis added]*.**"

According to the American College of Obstetrics and Gynecology's website, "The USPSTF recommendations are largely in line with current cervical cancer screening guidelines from the American College of Obstetricians and Gynecologists (ACOG);[1] ASCCP [American Society for Colposcopy and Cervical Pathology]; the American Cancer Society; and the American Society for Clinical Pathology;[2] and interim clinical guidance on hrHPV testing developed by an expert panel that included representatives from the aforementioned groups, the Society of Gynecologic Oncology, the American Society of Cytopathology, and the College of American Pathologists.[3] Like the USPSTF recommendations, these expert guidelines recognize that **cytology alone, hrHPV testing alone, and co-testing are all effective screening strategies** for average-risk women aged 30–65 years. However, ***expert guidelines recommend that for these women, co-testing with cervical cytology and hrHPV testing every 5 years is preferred (emphasis added)***, screening with cervical cytology alone every 3 years is acceptable, and hrHPV testing alone can be considered as an alternative screening strategy."[4]

Another reason it is inappropriate to eliminate co-testing from the cervical screening algorithm concerns HPV negative cervical carcinomas. A number of studies have found that 9-10% of invasive cancers will test negative for HPV by commercially available tests[4,5,6] and that 8.3-14% of high-grade squamous

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[1] Cervical cancer screening and prevention. Practice Bulletin No. 168. American College of Obstetricians and Gynecologists. Obstet. Gynecol. 20016; 128:e111-130.Avalable at http://journals.lww.com/greenjournal/fulltext/2016/10000/Practice_Bulletin_No__168___Cervical_Cancer.58.aspx

[2] Saslow, D, Solomon, D, Lawson HW Killackey M, Kulasingam SL, Cain J, et al. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. ACS-ASCCP-ASCP Cervical Cancer Guideline Committee. CA Cancer J Clin 2012;62:147-72. Available at https://onlinelibrary.wiley.com/doi/abs/10.3322/caac.21139

[3] Huh WK, Ault KA, Chelmow D, Davey DD, Goulart RA, Garcia FA, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: interim clinical guidance. Obstet Gynecol 2015;125:330–7. Available at: http://journals.lww.com/greenjournal/fulltext/2015/02000/Use_of_Primary_High_Risk_Human_Papillomavirus.8.asp

[4] Zhao C, Li Z, Nayar R, et al. Prior High-risk human papillomavirus testing and Papanicolaou test results of 70 invasive cervical carcinomas diagnosed in 2012: results of a retrospective multicenter study. Arch Pathol Lab Med 2015;139:184-188.

[5] Blatt AJ, Kennedy R, Luff R, Austin RM, Rabin DS. Comparison of cervical screening results among 256,648 women in multiple clinical practices. Cancer Cytopathol 2015;123:282-288.

[6] Zheng B, Li Z, Griffith CC, Yan S, Chen C, Ding X, Liang X, Yang H, Zhao C. Prior high-risk HPV testing and Pap test results for 427 invasive cervical cancers in China's largest CAP-certified laboratory. Cancer Cytopathol 2015;123:428–34.

intraepithelial lesion[7] (HSIL) cases may also be negative for high-risk HPV.[8, 9] Delayed diagnoses could then result in higher stage tumors due to the longer (5-year) screening intervals after negative HPV results.[10] The addition of cytology will add sensitivity as women diagnosed with cervical cancer may be more likely to be detected by liquid-based cytology than a positive HPV test.[11]

Due to the documentation of HPV-negative carcinomas as well as high grade lesions (HSIL/AIS), women should have a morphological examination (Pap test) at some time in their screening history and should not be screened solely with HPV tests. This is especially important for older women with an uncertain screening history or with any clinical symptoms.

In addition, ASCP and ASC are concerned that eliminating co-testing could, as a result of the absence of Pap testing, exacerbate the disparities in cervical cancer screening and detection in already underserved and vulnerable populations.

ASCP and ASC notes that excluding co-testing from this measure penalizes physicians who understand the importance of co-testing by inappropriately lowering their score on this critical patient care metric. The proposed change to this measure could also result in harm to patients and penalize physicians for providing appropriate patient care. We strongly urge CMS to rescind the proposed change to this measure.

ASCP represents the frontlines of laboratory diagnostics, and our membership of 100,000+ board certified pathologists, other physicians, and non-physician laboratory professionals lead the nation's efforts to diagnose and screen for COVID-19 and other diseases/conditions. ASCP is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

The ASC, founded in 1951, is a distinguished national professional society of physicians, cytotechnologists and scientist who are dedicated to the cytologic method of diagnostic pathology. The ASC is a 3,000 member professional organization dedicated to excellence in the practice of Cytopathology. The ASC's diverse membership includes representatives from other countries who share a vision of education, research and continuous improvement in the standards and quality of patient

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[7] Squamous cells on a Pap test that appear very abnormal and signify the possibility of a precancer or cancer of the cervix.

[8] Ge Y, Mody FF, Olsen RJ, et al. HPV status in women with high-grade dysplasia on cervical biopsy and preceding negative HPV tests. J Am Soc Cytopathol 2019;8:149-156.

[9] McCarthy E, Ye C, Smith M, Kurtycz DFI. Molecular testing and cervical screening: will one test fit all? J Am Soc Cytopathol 2019;5:331-338.

[10] Kinney W, Wright TC, Dinkelspiel HE, DeFrancesco M, Thomas Cox J, Huh W. Increased cervical cancer risk associated with screening at longer intervals. Obstet Gynecol 2015;125:311-315.

[11] *Kaufman HW, Alagia DP, Chen Z, Onisko A, Austin RM. Contributions of liquid-based cytology and human papillomavirus testing for detection of cervical cancer and precancer in the United States. Am J Clin Pathol 2020 (in press).*

care. The ASC is a unique society that provides a forum where physicians and cytotechnologists can interact and network with each other on both a personal and professional level.

We appreciate the opportunity to provide these comments. If we can be of any assistance in developing guidance on this matter or anything else, please do not hesitate to contact me or Matthew Schulze, Director of the ASCP Center for Public Policy, at (202) 735-2285.

Sincerely,

Kimberly Sanford, MD, MASCP, MT(ASCP)
President, American Society for Clinical Pathology

Daniel F. I. Kurtycz, MD
President, American Society of Cytopathology