December 17, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

As members of Congress and advocates for colorectal cancer (CRC) prevention and awareness, we extend our sincere gratitude to CMS for its commendable work expanding access to CRC screening. We appreciate CMS's decision to cover CRC screenings for Americans aged 45 and older, aligning with the US Preventive Services Task Force's (USPSTF) recommendations. Additionally, the decision to cover follow-on screening colonoscopies after a Medicare-covered, noninvasive stool-based CRC screening test returns a positive result is a critical step forward in improving outcomes related to CRC diagnosis.[1]

Despite these significant advancements, we are concerned about a critical barrier hindering effective CRC screening for patients, the cost-sharing associated with colonoscopy preparation medications. Colonoscopy, recognized as the gold standard for CRC screening, is essential in detecting and preventing the progression of this disease. However, the success of a colonoscopy is heavily dependent on the proper use of a laxative medication, commonly known as a "colonoscopy preparation," to safely and effectively cleanse a patient's intestines. CMS has recognized the importance of colonoscopy preparation as "an integral part of the procedure."[2]

Cost-sharing and cost shifting to patients, imposed by health plans for colonoscopy preparation, are contributing to disparities in CRC outcomes and a clinically recognized phenomenon called "prep hesitancy." In correlation with CRC screening being a recommended preventive service covered by health plans at no cost sharing under the Affordable Care Act (ACA), CMS released guidance in 2016 asserting that colonoscopy preps should be covered by plans under CMS' jurisdiction free-of-charge to patients, subject to "reasonable medical management".[3] Despite this, only 17% of patients are receiving colonoscopy preps with no cost sharing liability. There are many examples of ACA-compliant private health plans, particularly due to the business practices of their Pharmacy Benefit Managers (PBMs), inappropriately shifting costs onto patients for more effective and modern colonoscopy preparations.[4,5]

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[1] https://www.cms.gov/files/document/mm13017-removal-national-coverage-determination-expansion-coverage-colorectal-cancer-screening.pdf

[2] https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-31_final-4-20-16.pdf

[3] https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-31_final-4-20-16.pdf

[4] Shah, Eric D. MD, MBA, FACG[1]; Calderwood, Audrey H. MD, MS[2]; Halberg, Daniel L. PhD[3,*]; . S401 Contrary to ACA Mandate for Screening Colonoscopy, Most Colonoscopy Preps Result in Out-of-Pocket Costs for Patients – A Real World Analysis From a Large Dataset. The American Journal of Gastroenterology 118(10S):p S293, October 2023. | DOI: 10.14309/01.ajg.0000951244.69882.1d
https://journals.lww.com/ajg/fulltext/2023/10001/s401_contrary_to_aca_mandate_for_screening.757.aspx

[5] Shah, Eric D. Calderwood, AH, Halberg, DL. Tu1094 MOST SCREENING COLONOSCOPY PATIENTS HAVE OUT-OF-POCKET COSTS FOR COLON PREPS CONTRARY TO THE ACA MANDATE: A REAL-WORLD ANALYSIS FROM A LARGE DATASET Gastroenterology, Volume 166, Issue 5, S-1234

This often forces patients to use less effective, or over the counter, non-FDA approved products contributing to prep hesitancy and inadequate colonoscopy preparation. Prep hesitancy is recognized as a significant factor which contributes to 53% of patients with a positive stool-based CRC screening test never having a follow-up colonoscopy.[6] Studies also indicate that bowel preparation is inadequate in 15% to 35% of colonoscopies, with variations across medical settings and patient populations. Inadequate bowel preparation negatively affects the Adenoma Detection Rate (ADR) and, as CMS has identified, ADR is a validated leading quality indicator associated with significant protection against incident colorectal cancer in the five years following screening colonoscopy.[7,8] Other quality indicators of colonoscopy, such as cecal intubation rates are also negatively impacted by inadequate colonoscopy preparation.[9] Inadequate colonoscopy preparation also leads to longer procedure times, increased costs and worse outcomes for patients diagnosed with cancer.[10]

Additionally, cost-shifting and prep hesitancy are contributing to higher rates of inadequate CRC screening among medically underserved populations. For instance, when compared to white men, CRC death rates are 46% higher in Native American and Alaskan Native men and 44% higher in Black men, with incidence gaps of 37% and 21%, respectively. Additionally, participation in CRC screening is lower in all racial/ethnic minority groups compared to White individuals.[11]

In order to address this barrier in CRC screening, we urge CMS to:

- Restate the 2016 guidance specifying that colonoscopy preparations must be covered at no cost sharing for patients when prescribed for a screening colonoscopy and further specify that all FDA approved colonoscopy preparations that meet medical guideline established efficacy standards will be made available to patients at no cost.

- Review the plans under its jurisdiction to ensure enforcement of the above request to confirm compliance with the requirements of the ACA.

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[6] Mohl JT, Ciemins EL, Miller-Wilson LA, Gillen A, Luo R, Colangelo F. Rates of Follow-up Colonoscopy After a Positive Stool-Based Screening Test Result for Colorectal Cancer Among Health Care Organizations in the US, 2017-2020. *JAMA Netw Open.* 2023 Jan 3;6(1):e2251384. doi: 10.1001/jamanetworkopen.2022.51384. PMID: 36652246; PMCID: PMC9856942.

[7] CMS Measure #343: Screening Colonoscopy Adenoma Detection Rate – National Quality Strategy Domain: Effective Clinical Care.

[8] Douglas K Rex, Philip S Schoenfeld, Jonathan Cohen, Irving M Pike, Douglas G Adler, M Brian Fennerty, John G Lieb 2nd, Walter G Park, Maged K Rizk, Mandeep S Sawhney, Nicholas J Shaheen, Sachin Wani, David S Weinberg. Gastrointest Endosc. 2015 Jan;81(1):31-53. doi: 10.1016/j.gie.2014.07.058.

[9] Sharma P, Burke CA, Johnson DA, Cash BD. The importance of colonoscopy bowel preparation for the detection of colorectal lesions and colorectal cancer prevention. Endosc Int Open. 2020 May;8(5):E673-E683. doi: 10.1055/a-1127-3144. Epub 2020 Apr 17. PMID: 32355887; PMCID: PMC7165013.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7165013/.

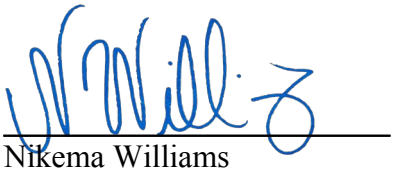
[10] *Rex, Douglas K MD; Schoenfeld, Philip S MD, MSEd, MSc (Epi); Cohen, Jonathan MD; Pike, Irving M MD; Adler, Douglas G MD; Fennerty, Brian M MD; Lieb, John G MD; Park, Walter G MD, MS; Rizk, Maged K MD; Sawhney, Mandeep S MD, MS; Shaheen, Nicholas J MD, MPH; Wani, Sachin MD; Weinberg, David S MD, MSc. Quality Indicators for Colonoscopy. American Journal of Gastroenterology 110(1):p 72-90, January 2015. | DOI: 10.1038/ajg.2014.385.*
https://journals.lww.com/ajg/fulltext/2015/01000/Quality_Indicators_for_Colonoscopy.13.aspx/1000

[11] McLeod MR, Galoosian A, May FP. Racial and Ethnic Disparities in Colorectal Cancer Screening and Outcomes. *Hematol Oncol Clin North Am*. 2022 Jun;36(3):415-428. doi:10.1016/j.hoc.2022.02.003. Epub 2022 Apr 30. PMID: 35504786.

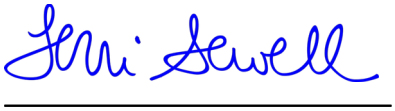
- Determine whether additional rulemaking is needed to bring noncompliant plans into compliance.

These measures would not only enhance access to screening for Americans enrolled in ACA-compliant plans but would also influence other payers to close gaps in coverage for more effective colonoscopy preparation products. By removing barriers and costs associated with CRC screening, we believe that these measures would make a significant impact in turning the tide against colorectal cancer.

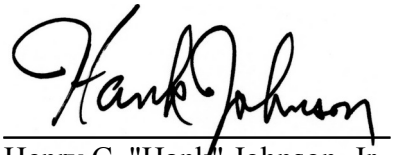
Sincerely,



Nikema Williams
Member of Congress



Terri A. Sewell
Member of Congress



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Dwight Evans
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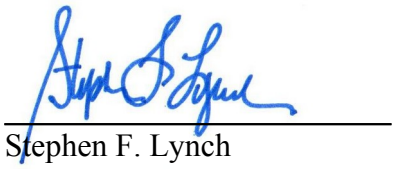
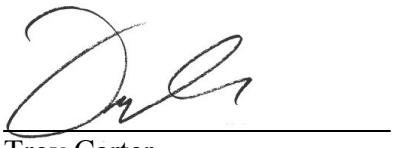
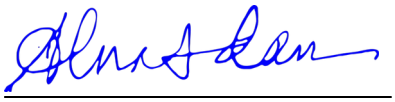


Stephen F. Lynch
Member of Congress



Troy Carter
Member of Congress



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