September 9, 2024

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1809-P – Medicare and Medicaid Programs; Hospital Outpatient Prospective Payment System Proposed Rule
89 Fed. Reg. 59186 (July 22, 2024)

Dear Secretary Becerra and Administrator Brooks-LaSure:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the calendar year 2025 Medicare Hospital Outpatient Prospective Payment System proposed rule. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's (ACS) nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN offers comments on the following proposals:

- All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities
- Coverage Changes for Colorectal Cancer (CRC) Screening Services
- Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)
- Medicaid Clinic Services Four Walls Exceptions

X. NONRECURRING CHARGES

C. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Cancer is a disease that affects everyone but does not affect everyone equally. Nationally, American Indian and Alaska Native (AI/AN) people have the highest incidence and mortality of

any population for cancers of the colorectum, kidney, liver, lung, and bronchus.[1,2] Cervical cancer incidence rates are highest among AI/AN people, and cervical mortality rates are highest for both AI/AN and Black people.[3] Additionally, AI/AN people are twice as likely to live in poverty as those who are white, regardless of where they live, and, compared to their white counterparts, are also more than twice as likely to be uninsured.[4] This is in part because of their reliance on critically underfunded Indian Health Service (IHS) services. Lastly, AI/AN individuals have a higher prevalence of many chronic health conditions than any other racial or ethnic group.[5]

CMS proposes to pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the all-inclusive rate (AIR). CMS emphasizes that the amount of this proposed payment would be additive and would not be carved out of the annual AIR payment amount calculation.

CMS also proposes that the drugs to which the add-on payment would apply include both high-cost oncology drugs and other drugs furnished in hospital outpatient departments of IHS and tribal hospitals. Add-on payments would apply only to the extent those drugs are covered under Medicare Part B and would be paid for under the Hospital Outpatient Prospective Payment System (OPPS) if furnished by a hospital paid under that system. Applying the add-on payment to all high-cost drugs was also done in part to eliminate the possibility of unintentionally excluding an oncology drug from separate payment due to the inherent challenge of defining a class of drugs.

ACS CAN supports this provision to increase access to high-cost drugs and cancer treatment at IHS and Tribal hospitals. This proposed rule is important because while the majority of IHS and Tribal facilities appear to be well served by the AIR, some IHS and Tribal facilities that provide specialized services for which the AIR might not adequately represent Medicare's share of costs means that the current model is not financially feasible for facilities to routinely provide those drugs or services. The IHS, the primary health care service for many AI/ANs, is underfunded and understaffed and ACS CAN continues to support increased funding levels for the agency to reduce health disparities for AI/AN and other Indigenous communities.

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[1] American Cancer Society. *Cancer Facts & Figures 2024. Atlanta: American Cancer Society; 2024*.
[2] The American Cancer Society published a Special Section on Cancer in the American Indian and Alaska Native population in the 2022 Cancer Facts & Figures that is available online at https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-special-section-aian.pdf.
[3] *Cancer Facts & Figures 2024.*
[4] Special Section on Cancer in the American Indian and Alaska Native population in the 2022 Cancer Facts & Figures.
[5] Cromer KJ, Wofford L, Wyant DK. Barriers to Healthcare Access Facing American Indian and Alaska Natives in Rural America. J Community Health Nurs. 2019;36: 165-187.

D. COVERAGE CHANGES FOR COLORECTAL CANCER (CRC) SCREENING SERVICES

Consistent with the proposed changes in the calendar year 2025 Medicare Physician Fee Schedule proposed rule, CMS seeks to amend coverage of colorectal cancer screenings by removing coverage for the barium enema procedure, adding coverage for the computed tomography colonography (CTC) procedure, and expanding the existing definition of a "complete colorectal cancer screening" to include a follow-on screening colonoscopy after a Medicare covered blood-based biomarker CRC screening test (as authorized in NCD 201.3).

ACS CAN strongly supports these proposals. In 2024, an estimated 106,590 cases of colon cancer will be diagnosed in the United States, a majority of which will be diagnosed in individuals aged 45 and older.[6] An estimated 53,010 people will die from the disease this year.[7] Colorectal cancer remains one of the deadliest forms of cancer.[8] Regular screening is the most effective way of detecting precancerous growths and early colorectal cancer. Removal of precancerous lesions can prevent colorectal cancer and cancers found at an early stage can be treated more easily, and lead to greater survival.[9] For colorectal cancer, the five-year survival rate is approximately 90 percent for patients aged 65 and older whose cancer is discovered and treated early. In contrast, individuals aged 65 and older whose colorectal cancer is found at a later stage, after the cancer has metastasized, have a 10 percent five-year survival rate.[10]

Remove coverage of barium enema: CMS is proposing to no longer cover barium enema as a colorectal cancer screening test because this procedure no longer meets clinical standards.

ACS CAN supports CMS' decision to no longer cover barium enema as a colorectal cancer screening test. As noted in the proposed rule the American Cancer Society's 2018 colorectal cancer screening guidelines no longer recommend barium enemas as an acceptable screening option.[11] Similarly the U.S. Preventive Services Task Force most recent colorectal cancer screening recommendation, which was issued in 2021, also does not recommend barium enemas as an appropriate screening modality.[12] We believe there are other colorectal cancer screening modalities that provide beneficiaries and their providers with better options to detect colorectal cancer.

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[6] *Cancer Facts & Figures 2024*.
[7] American Cancer Society. *Colorectal Cancer Facts & Figures 2020-2022*. Atlanta: American Cancer Society; 2020.
[8] Siegal RL, Miller KD, Fuchs HE Jemal A. Cancer statistics, 2021. *Cancer.* 2021; 71:7-33, doi 10.3322/caac.21654.
[9] American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2023-2024*. Atlanta: American Cancer Society; 2024.
[10] American Cancer Society. *Colorectal Cancer Facts & Figures 2023-2025*. Atlanta: American Cancer Society; 2024.
[11] Wolf, A.M.D., Fontham, E.T.H., et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. CA: A Cancer Journal for Clinicians, 68: 250-281. https://doi.org/10.3322/caac.21457.
[12] U.S. Preventive Services Task Force. Screening for colorectal cancer: US Preventive Services Task Force recommendation statement. 2021. JAMA. 2021;325(19):1965-1977. doi:10.1001/jama.2021.6238 Corrected on August 24, 2021.

Coverage of the CT Colonography (CTC): CMS proposes to add CT colonography (CTC) as a Medicare-covered colorectal cancer screening test. CMS proposes to limit coverage of CTC based on the risk profile of the beneficiary. Individuals who are not at high risk of developing colorectal cancer could receive a CTC once every 5 years or 4 years since the last screening flexible sigmoidoscopy or screening colonoscopy. Individuals who are at high risk of colorectal cancer could receive a screening CTC every 2 years or 2 years after the last screening colonoscopy was performed. CMS clarified that if the proposal were adopted, beneficiaries would not face cost sharing for any screening CTC but would face cost sharing if the procedure were performed for purposes other than as a screening for colorectal cancer.

ACS CAN applauds CMS' proposal to cover CT colonography, which will provide another minimally invasive colorectal cancer screening modality to help detect colorectal cancer. Specifically, beneficiaries who desire a non-invasive imaging option for screening may choose CT colonography.

With respect to the frequency of testing for individuals who are at average risk, we do not believe that coverage of a CT colonography 47 months after a screening colonoscopy was performed is necessary. Screening intervals relate to the next occasion of the same screening test after a normal examination. If a Medicare beneficiary of average risk has had a normal screening colonoscopy, then their next screening interval would be 10 years. If at the end of this 10-year period, the individual elects to undergo a CT colonoscopy, they should be given the opportunity to do so (in consultation with their medical provider) but electing a CT colonoscopy does not negate the recommended screening intervals for colonoscopies. Thus, CMS should clarify that coverage of CT colonography for individuals of average risk should be 10 years following the last screening colonoscopy.

With respect to individuals who are at high risk, it is recommended that these individuals receive a colonoscopy given that screening with a different modality often results in the need for a follow-up colonoscopy. However, we support CMS' proposed coverage of CT colonography for this population because it provides an alternative for those who do not wish to have a colonoscopy.

Expand the definition of a "complete colorectal cancer screening": In the CY 2023 Physician Fee Schedule final rule CMS expanded the definition of a complete colorectal cancer screening to include a follow-on colonoscopy after a positive result from a Medicare-covered non-invasive stool-based colorectal cancer screening test (i.e., a Fecal Occult Blood Test (FOBT), a Multi-target Stool DNA (sDNA) test, or a Blood-based biomarker test). CMS now proposes to further expand the definition of complete colorectal cancer screening to also include a Medicare covered blood-based biomarker colorectal cancer screening test consistent with the coverage parameters set forth in NCD 210.3.[13]

[13] Medicare National Coverage Determination 210.3. Colorectal cancer screening tests. Effective Jan. 1, 2023. Available from https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=281.

ACS CAN strongly supports CMS' proposed expansion of a complete colorectal screening. This proposal will remove cost-sharing for follow-up colonoscopies following a positive non-invasive test. Removing this cost-sharing will help to ensure that enrollees complete the recommended colorectal cancer screening continuum.

This proposal is also consistent with the position of the American Cancer Society (ACS), which has asserted for many years, and stated in ACS' screening guidelines,[14] that cancer screening should be understood as a continuum of testing rather than a single recommended screening test and should include all follow up tests judged to be integral and necessary to resolve the question of whether an adult undergoing screening has cancer.[15]

At this time there is currently only one FDA-approved blood-based biomarker colorectal cancer screening test on the market and CMS determined that test does not meet the criteria for coverage.[16] As more research is being undertaken to develop new blood-based colorectal cancer screening tests, at some future point there may be a blood-based test that will meet CMS' criteria for coverage. CMS' proposal will allow the agency to ensure coverage of follow-ups immediately after CMS approves coverage of a blood-based colorectal cancer screening test that meets Medicare's coverage requirements.

Once CMS finalizes its coverage of CT colonography, as discussed above, we urge the Agency to also clarify that the definition of complete colorectal cancer screening also includes coverage of follow-up colonoscopies performed after a CT colonography. CMS should clarify that it will cover a follow-up colonoscopy performed after any Medicare-covered colorectal cancer screening. This will ensure that Medicare beneficiaries have access to a complete colorectal cancer screening, regardless of the initial modality used.

New Colorectal Cancer Screening Tests: Geneoscopy's multi-target mRNA stool test and Guardant Health's shield blood test have recently been approved by the FDA for colorectal cancer screening in adults aged 45 and older who are at average risk for the disease. These are non-invasive screening tests, which if positive, will require follow-on colonoscopies for the completion of the screening. We urge CMS' Coverage and Analysis Group's to swiftly review to determine coverage of these, and subsequent FDA-approved tests, which could provide yet another evidence-based colorectal cancer screening option for individuals.

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[14] Fontham ETH, Wolf AMD, Church TR, Etzioni R, et al. Cervical Cancer Screening for Individuals at Average Risk: 2020 Guideline Update From the American Cancer Society. CA Cancer J Clin. 2020; 321-346. doi:10.3322/caac.21628.

[15] American Cancer Society. American Cancer Society position statement on the elimination of patient cost-sharing associated with cancer screening and follow-up testing. Feb 26, 2023. Available from https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/overview/acs-position-on-cost-sharing-for-screening-and-follow-up.html.

[16] Centers for Medicare & Medicaid Services. Decision Memo: Screening for colorectal cancer – blood based biomarker tests. CAG-00454N. Jan. 19, 2021.

XX. PROVISIONS RELATED TO MEDICAID AND THE CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

ACS CAN commends CMS for the proposed updates to Medicaid and CHIP regulations that align with the Consolidated Appropriations Act (CAA) of 2023. CMS proposes to mandate continuous eligibility (CE) for children enrolled in Medicaid and CHIP, requiring states to provide 12 months of continuous coverage for children under the age of 19, regardless of changes in circumstances that might otherwise impact their eligibility. CMS also proposes to eliminate the previous state options to limit CE by setting an age lower than 19 or by providing a CE period shorter than 12 months. Additionally, CMS would remove the option for states to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during the continuous eligibility period.

Mandatory Continuous Eligibility: ACS CAN strongly supports mandatory CE for children in Medicaid and CHIP, as proposed. Continuous eligibility in these programs is a vital policy that reduces the risk of coverage disruptions due to fluctuations in family income or other circumstances, which can negatively impact a child's access to necessary healthcare services. Data from the Urban Institute shows that continuous eligibility policies reduce the rate of uninsured children by 24% in states that have implemented these measures.[17] Research from Georgetown University's Center for Children and Families highlights that continuous eligibility helps prevent "churn," where children lose and regain coverage within short periods, thereby ensuring that children receive consistent healthcare services.[18] By eliminating the state options to limit CE by age or duration, CMS ensures a uniform standard of coverage across all states, providing equitable access to healthcare for children regardless of where they live.

Prohibiting Disenrollment for Failure to Pay Premiums: ACS CAN also supports the proposed removal of the option for states to disenroll children from separate CHIP coverage for failure to pay required premiums or enrollment fees during a continuous eligibility period. We recognize the financial challenges many families face, particularly those with children who have chronic or life-threatening illnesses.

Data from the Kaiser Family Foundation (KFF) indicates that low-income families, especially those with children who have chronic conditions, often face significant financial barriers to maintaining health insurance coverage.[19] Even small premium increases can lead to a decrease in enrollment among these families, making the removal of disenrollment for non-payment during a continuous eligibility period critical. A study published in JAMA Pediatrics found that

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[17] Urban Institute. (2020). *The effects of continuous eligibility on children's Medicaid coverage and outcomes.* Retrieved from https://www.urban.org/sites/default/files/publication/104785/what-will-happen-to-unprecedented-high-medicaid-enrollment-after-the-public-health-emergency_0.pdf.

[18] Georgetown University Center for Children and Families. (2021). Continuous eligibility in Medicaid and CHIP: Ensuring consistent coverage for children. https://ccf.georgetown.edu/2022/10/07/medicaid-and-chip-continuous-coverage-for-children/.

[19] Kaiser Family Foundation. (2021). *Understanding the Impact of Medicaid Premiums & Cost-Sharing. https://www.kff.org/medicaid/issue-brief/understanding-the-impact-of-medicaid-premiums-cost-sharing-updated-evidence-from-the-literature-and-section-1115-waivers/*.

gaps in insurance coverage are associated with delays in care and unmet medical needs in children, reinforcing the importance of maintaining continuous coverage to ensure children receive timely and necessary medical care.[20]

ACS CAN applauds CMS's efforts to strengthen the Medicaid and CHIP programs by ensuring continuous coverage for children under the age of 19. We believe that these proposed changes, supported by evidence showing the benefits of continuous eligibility, will significantly improve health outcomes for children across the country and reduce the administrative complexity for states and families alike. We hope that CMS also considers the importance of implementing enhanced outreach and education efforts to inform families about these changes, providing robust technical assistance to states during the transition to the new continuous eligibility requirements, and ensuring strong monitoring and enforcement mechanisms to prevent unauthorized disenrollment practices and maintain compliance with the new rules.

XVIII. MEDICAID CLINIC SERVICES FOR FOUR WALL EXCEPTIONS

CMS is proposing to amend the Medicaid clinic services regulation to authorize federal reimbursement for services furnished outside the "four walls" of a freestanding clinic by IHS and Tribal clinics. This change would be mandatory for all states that opt to cover Medicaid clinic services and allows for these clinics to bill at the facility rate, which would generally be the AIR for IHS and tribal clinics. ACS CAN supports this proposed change to remove barriers to accessing care for marginalized AI/AN populations as it helps ensure that individuals can receive the necessary services they need regardless of their ability to visit a clinic in-person.

CMS also proposes an optional exception for clinics located in rural areas, allowing them to offer services outside the clinic walls. This change aims to improve access to healthcare services for residents in rural areas who often lack access due to distance and transportation challenges. States can choose to adopt this exception to better serve their rural populations. People facing cancer and survivors who live in rural communities are more likely to have limited incomes and to die from cancer than their urban counterparts.[21] According to researchers at the ACS, mortality from all-cancer and leading causes of cancer death are substantially higher in non-metropolitan areas than in large metropolitan areas and in individuals with limited education.[22] ACS CAN supports this exception as an option for states to reduce cancer disparities in AI/AN and rural communities.

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[20] Hudson, J. L., & Moriya, A. S. (2017). Medicaid Expansion For Adults Had Measurable 'Welcome Mat' Effects On Their Children. Health affairs (Project Hope), 36(9), 1643–1651. https://doi.org/10.1377/hlthaff.2017.0347.
[21] American Cancer Society Cancer Action. *The Costs of Cancer in Rural Communities*; 2022.
[22] Islami F, Baeker Bispo J, Lee H, et al. American Cancer Society's report on the status of cancer disparities in the United States, 2023. CA Cancer J Clin. 2024; 74(2): 136-166. doi:10.3322/caac.21812.

CONCLUSION

Thank you for the opportunity to comment on the Medicare Hospital Outpatient Prospective Payment System proposed rule. If you have any questions, please feel free to contact me or have your staff contact Gladys Arias, Principal, Health Equity Policy Analysis & Legislative Support at Gladys.Arias@cancer.org or Anna Schwamlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org.

Sincerely,

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network