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-1807-P – Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Coverage Policies
89 Fed. Reg. 61596 (July 31, 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 (CY) 2025 Medicare Physician Fee Schedule 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 policies:

- Payment for Medicare Telehealth Services
- Request for Information on Services Addressing Principal Illness Navigation
- Medicare Diabetes Prevention Program
- Expanded Colorectal Cancer Screening
- MIPS Quality Measure Changes: Lung Cancer Screening

II. Provisions of the Proposed Rule

D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

CMS is proposing several changes to the Medicare telehealth services list.

1. Payment for Medicare telehealth services under section 1834(m) of the Act

e. Audio-only communication technology to meet the definition of "telecommunications systems"

CMS is proposing to revise its existing regulations to state that an interactive telecommunications system may also include two-way, real-time audio-only communications technology for any telehealth service furnished to a beneficiary in their home of the distant site physician or practitioner is technologically capable of using an interactive telecommunications system that at a minimum includes audio and video equipment permitting the two-way, real-time interactive communication but the

patient is not capable of, or does not consent to, the use of video technology.

ACS CAN supports this policy. We support the use of telehealth services, where appropriate, because telehealth can play a beneficial role across the cancer continuum: prevention and screening, diagnosis, treatment (including clinical trials), and survivorship. Telehealth has an important role to play in improving health equity by increasing access to quality cancer care among communities that have been marginalized, e.g., residents of rural communities, individuals with limited income, patients with low health literacy, and people of color. Telehealth can also extend the reach of navigation services to populations that have been underserved so that they can access resources that help eliminate other barriers to care. We support CMS' decision to permit the use of audio-only telecommunications to allow beneficiaries who lack reliable access to internet services to enjoy the benefits of telehealth if they choose to do so.

E. Valuation of Specific Codes

40. Request for Information for Services Addressing Health-Related Social Neets (Community Health Integration (G0019, G0022), Principal Illness Navigation (G0023, G0024), Principal Illness Navigation-Peer Support (G0140, G0146), and Social Determinants of Health Risk Assessment (G0136)

In the CY 2024 Physician Fee Schedule, CMS finalized the creation of four new principal illness navigation (PIN) codes – G0023,G0024, G0140, and G0146 – which for the first time in the program's history provided reimbursement for critically important navigation services. Research has shown that the use of navigation services can help to improve care and reduce costs for patients, providers and the larger health care system.[1] CMS is now issuing a broad request for information PIN services. ACS CAN offers the following comments as CMS considers building upon existing PIN services.

Telehealth List: We appreciate CMS clarifying that the PIN codes were not added to the Medicare Telehealth List because these services are ordinarily furnished outside of an in-person, face-to-face visit, and so are outside the scope of Medicare telehealth services and therefore are not necessary to add to the Medicare Telehealth Services List. Still, we encourage CMS to continue to monitor whether excluding PIN services from the telehealth list creates any limitation on providing these services and revisit the decision, if needed.

Waive beneficiary cost sharing obligations: PIN services have been shown to improve patient outcomes, reduce unnecessary treatment costs and increase patient satisfaction. However, under current Medicare requirements, beneficiaries are charged cost sharing for PIN services. Research has shown that the imposition of cost sharing can be a significant barrier for individuals who need preventive services,[2] particularly for people with limited incomes for whom cost sharing can represent a significant financial hardship. We urge CMS to work with Congress to waive cost sharing for valuable

[1] Dwyer AJ, Wender RC, Weltzien ES, Dean MS, Sharpe K, Fleisher L, Burhansstipanov L, Johnson W, Martinez L, Wiatrek DE, Calhoun E, Battaglia TA; National Navigation Roundtable. Collective pursuit for equity in cancer care: The National Navigation Roundtable. Cancer. 2022 Jul 1;128 Suppl 13:2561-2567. doi: 10.1002/cncr.34162. PMID: 35699616.

[2] Han X, Robin Yabroff K, Guy GP, Zheng Z, Jemal A. Has recommended preventive service use increased after elimination of cost-sharing as part of the Affordable Care Act in the United States? Prev Med. 2015 Sep;78:85-91. doi: 10.1016/j.ypmed.2015.07.012.

coordination of care services such as PIN services.

Expand providers who can bill PIN services: As patients progress along their treatment journey, they can have times of appropriate overlapping care among various providers. Unfortunately, only one provider can bill for these services in a 30-day period. This limitation prevents patients from experiencing the full benefit of PIN services. ACS CAN urges CMS to allow more than one billing practitioner per month per eligible condition with the additional requirement that the concurrent care be documented by both billing practitioners as necessary for the patient's treatment plan.

Certification of auxiliary personnel in PIN services: We encourage CMS to explore reimbursement pathways for PIN services that also provide prevention and screening services, if these services are not covered under any proposed changes to the Community Health Integration (CHI) codes. We recommend that CMS clarify that PIN training requirements apply to both certified and non-certified auxiliary personnel to demonstrate that they are providing PIN services that are eligible for reimbursement.

Additionally, in response to the CMS inquiry for what types of auxiliary personnel typically furnish PIN services, the most common job titles held by those engaged in the American Cancer Society's Leadership in Oncology Navigation (ACS LION) training and credentialing program include: patient navigator/nonclinical navigator, oncology nurse navigator, social worker, registered nurse, and nonclinical coordinator.

Community Based Organization (CBO) collaboration with billing practitioners: CMS is interested in how CBOs are collaborating with billing practitioners, including current or planned contracting arrangements, and if there is anything else CMS should do to clarify services where auxiliary personnel can be employed by CBOs.

We appreciate CMS' ongoing encouragement that CBOs engage in contracts with qualified providers to deliver patient navigation services as well as the incorporation of CBOs into PIN code payment through "incident to" billing but recognize this means that funding for these services only goes directly to the billing providers and not the collaborating CBO(s). CMS should encourage subcontracting with CBOs to ensure funding includes CBOs. We recommend that CMS encourage Medicare to take advantage of the opportunity to engage CBOs, because they are often underfunded and under-resourced organizations, to ensure these critical providers remain sustainable and make these services more accessible to the communities that need these services most.

Related services not described by the current coding: The proposed rule also currently limits PIN services to services that practitioners would only provide during active cancer treatment (i.e., services for a serious, high-risk condition expected to last at least 3 months that places the patient at significant risk of hospitalization, acute exacerbation, functional decline or death). Although PIN services during active cancer treatment are vital, PIN services can also be instrumental throughout a patient's cancer journey starting with prevention, early detection, diagnosis and into survivorship. We encourage CMS to explore reimbursement pathways for PIN services that also provide prevention and screening services as well as aspects of survivorship care, if these services are not covered under any proposed changes to the Community Health Integration (CHI) codes.

III. OTHER PROVISIONS OF THE PROPOSED RULE

E. Medicare Diabetes Prevention Program (MDPP)

1. Proposed changes to MDPP conditions of coverage (§410.79)

CMS proposes a number of conforming changes to the Medicare Diabetes Prevention Program (MDPP) to ensure consistency with this program and the CDC Diabetes Prevention Recognition Program (DPRP) Standards.

ASC CAN supports these changes as they provide greater flexibility in the delivery of MDPP services. By incorporating terms such as "in-person with a distance learning component" and "combination with an online component," CMS allows for varied methods of participation, which can accommodate beneficiaries facing barriers to in-person attendance. Aligning MDPP delivery modes with CDC DPRP standards ensures consistency and streamlines the administrative process for MDPP suppliers. Evidence shows that flexible delivery methods can improve program adherence and outcomes.[3]

2. Proposed changes to alternatives to the requirement for in-person weight measurement (§410.79(e)(3)(iii)

CMS proposes to revise its requirements to allow more flexibility to document the weight of MDPP beneficiaries. Specifically, self-reported weights can be obtained via live, synchronous online video technology, two date-stamped photos, or a video recording submitted by the beneficiary.

ACS CAN commends these revisions as they address practical challenges beneficiaries may face in attending in-person sessions for weight verification, especially during public health emergencies. Research shows that remote monitoring of health metrics, including weight, can be as effective as in-person monitoring and increases patient engagement.[4] Providing flexibility in weight documentation ensures that the program remains accessible while maintaining the integrity of the data collected.

K. Expanded Colorectal Cancer Screening

CMS is proposing several improvements to its coverage of colorectal cancer screening. 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.[5] An estimated 53,010 people will die from the disease this year.[6] Colorectal cancer remains one of the deadliest forms of cancer.[7]

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[3] Ely, E. K., Gruss, S. M., Luman, E. T., Gregg, E. W., Ali, M. K., Nhim, K., Rolka, D. B., & Albright, A. L. (2017). A National Effort to Prevent Type 2 Diabetes: Participant-Level Evaluation of CDC's National Diabetes Prevention Program. Diabetes care, 40(10), 1331–1341. https://doi.org/10.2337/dc16-2099.

[4] Hales, S., Turner-McGrievy, G. M., Wilcox, S., Davis, R. E., Fahim, A., Huhns, M., & Valafar, H. (2017). Trading pounds for points: Engagement and weight loss in a mobile health intervention. Digital health, 3, 2055207617702252. https://doi.org/10.1177/2055207617702252.

[5] American Cancer Society. *Cancer Facts & Figures 2024*. Atlanta: American Cancer Society; 2024.

[6] American Cancer Society. *Colorectal Cancer Facts & Figures 2020-2022*. Atlanta: American Cancer Society; 2020.

[7] Siegal RL, Miller KD, Fuchs HE Jemal A. Cancer statistics, 2021. *Cancer.* 2021; 71:7-33, doi 10.3322/caac.21654.

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.[8] 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.[9]

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.[10] 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.[11] We believe there are other colorectal cancer screening modalities that provide beneficiaries and their providers with better options to detect colorectal cancer.

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

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[8] American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures 2023-2024*. Atlanta: American Cancer Society; 2024.
[9] American Cancer Society. *Colorectal Cancer Facts & Figures 2023-2025*. Atlanta: American Cancer Society; 2024.
[10] 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.
[11] 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.

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.[12]

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,[13] 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.[14]

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.[15] 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.

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[12] 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.

[13] 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.

[14] 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.

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

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.

IV. UPDATES TO THE QUALITY PAYMENT PROGRAM

G. MIPS Performance Categories, Measures and Activities

3. Improvement activities (IA) performance category

CMS proposes to add a new improvement activity to the population management subcategory: Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Update. This would allow MIPS-eligible clinicians to receive credit for establishing a process or procedure to increase rates of lung cancer screening.

ACS CAN supports the addition of this new improvement activity. In 2024, an estimated 234,580 new cases of lung cancer will be diagnosed in the United States and 125,070 will die from the disease.[16] Lung cancer remains one of the deadliest cancers for both males and females.[17] While annual lung cancer screening (LCS) with low-dose chest computed technology (LDCT) has been recommended since 2016, few individuals who are eligible are screened annually. In fact, only 18% of eligible U.S. adults reported having undergone a LDCT of their lungs in 2022, and the rate of reporting a recent LDCT was highly variable across states.[18] We believe that including lung cancer screening as an improvement activity to the population management subcategory is urgently needed to help increase screening rates.

[16] Cancer Facts & Figures 2024.
[17] Id.
[18] Bandi P, Star J, Ashad-Bishop K, Kratzer T, Smith R, Jemal A. Lung Cancer Screening in the US, 2022. JAMA Intern Med. 2024 Aug 1;184(8):882-91.

CONCLUSION

Thank you for the opportunity to comment on the CY2025 Medicare Physician Fee Schedule proposed rule. If you have any questions, please feel free to contact me or have your staff contact 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