American Lung Association. | Celebrating 120 Years of Impact

September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

The American Lung Association is pleased to submit comments in response to the Centers for Medicare and Medicaid Services (CMS) proposed changes to the calendar year (CY) 2025 Medicare Physician Fee Schedule (MPFS).

The American Lung Association is the oldest voluntary health organization in the United States. For 120 years, the Lung Association has been working to save lives by improving lung health and preventing lung disease through education, advocacy and research. The Lung Association works on behalf of more than 36 million individuals in the U.S. living with and at risk for lung diseases including lung cancer, asthma and COPD.

Provisions Related to Medicaid and the Children's Health Insurance Program (CHIP)

The Lung Association strongly supports implementing the provisions related to Section 5112 of Title V, subtitle B of the Consolidated Appropriations Act, 2023. Continuous eligibility protects patients and families from gaps in care and promotes health equity.[1] Research has shown that individuals with disruptions in coverage during a year are more likely to delay care, receive less preventive care, refill prescriptions less often, and have more emergency department visits.[2] Gaps in Medicaid coverage have also been shown to increase hospitalizations and negative health outcomes for conditions including respiratory diseases.[3] Furthermore, studies show that children of color are more likely to be affected by gaps in coverage that continuous eligibility would address, rendering it crucial for increasing equitable access to care.[4] Overall, multi-year continuous coverage would improve access to and continuity of care for children during the critical early years of life[5] while promoting health equity.

Request for Information for Services Addressing Health-Related Social Needs

Navigating any serious diagnosis – especially lung cancer – can be daunting. About every two and a half minutes, someone in the U.S. is diagnosed with lung cancer; close to 238,000 people in the U.S. will be diagnosed with lung cancer this year. There are many steps from discovering a lung nodule to diagnosis, staging, and treatment and the Lung Association's Lung Helpline

and Lung Health Navigators are one resource to help answer any questions a person or their family may have.[6]

CMS asks for feedback on the services addressing health-related social needs. This includes principal illness navigation (PIN) services, which were implemented in January 2024. PIN services are care management, that include helping patients understand their diagnosis and care plan as well as navigate the healthcare system. Under the current CMS regulations, to be eligible for PIN services, a person must have a serious condition that is expected to last at least three months or longer and puts the patient at risk of hospitalization, nursing home placement, a sudden worsening of symptoms, physical or mental decline or death. The Lung Association supports PIN services for this population to better understand their care and navigate the healthcare system, however, the Lung Association believes PIN services should also be expanded to help patients navigate the cancer screening process as well.

For 2025, CMS is specifically seeking comment on any related services that may not be described by the current coding and that are medically reasonable and necessary "for diagnosis or treatment of illness or injury." The Lung Association urges CMS to include navigating lung cancer screening as an eligibility criterion for PIN services. Screenings are a medically reasonable and necessary step in diagnosing cancer.

Screening is the first step to an early, more treatable cancer diagnosis and unfortunately, lung cancer screening rates are incredibly low. While lung cancer is the leading cancer killer of both women and men in the U.S., accounting for approximately 22% of cancer deaths, reports shows that only 5.8% of eligible Americans have been screened for lung cancer. In some states screening rates are as low as 1%.[7,8] Low dose computed tomography (LDCT) screening for those at high risk for lung cancer increases early detection and can reduce the lung cancer death rate by up to 20%.[9] Detecting lung cancer in early stages versus late stage is often the difference between life and death. Unfortunately, racial and ethnic disparities exist in lung cancer treatment, leading to lower overall survival rates for Black and Latino individuals with a lung cancer diagnosis.[10]

A number of factors play into why screening rates for lung cancer are so low, including lack of awareness among providers regarding screening criteria and stigma. Additionally, as is true of other cancers, screening is often only the first step in diagnosing lung cancer. After the initial CT scan, follow-up diagnostic testing is needed to determine if a screening irregularity is or is not cancer. Additional steps and additional costs, compounded by the anxiety and fear of the results, can often cause a person to not complete the full continuum of services needed to diagnosis lung cancer. Navigators can help individuals overcome these barriers.

As is noted above, the Lung Association's HelpLine, which in addition to helping individuals navigate where to go and what to do after a lung cancer diagnosis, also utilizes Lung Health Navigators to help individuals determine if they are eligible for screening and to guide them each step of the way. Through the Lung Health Navigators, individuals can receive guidance on how to find screening centers; financial support for screenings (in qualifying states); scheduling assistance; financial assistance for transportation to/from LDCT; and tobacco cessation referrals and support.

The Lung Association believes lung cancer screening rates would be improved by allowing PIN services for patients navigating lung cancer screening. PIN services would help patients through

the logistics and better prepare them for treatment if necessary. The Lung Association also believes PIN services for lung cancer screening could help reduce the disparities in early diagnosis and survival of lung cancer in the Black and Latino communities, improving health equity. For many cancers, including lung cancer, there are evidence-based criteria that outline who is at high-risk and therefore, should be screened. Although there may not yet be a determination that an individual *has* a serious high-risk condition, the Lung Association can attest that the use of navigators to help individuals access lung cancer screening services increases uptake.

When CMS first announced the then-new PIN services, the agency highlighted the alignment with the Cancer Moonshot. Just recently, HHS announced another round of grants through the Health Resources and Services Administration's (HRSA) Accelerating Cancer Screening Award, which was created as part of the Cancer Moonshot in 2022. The funding will leverage outreach specialists and patient navigators to conduct engagement in underserved communities to promote early cancer detection, connect people to screening services, and provide assistance accessing follow-up treatment – allowing reimbursement of PIN services to be used for navigation related to cancer screenings would only be in further alignment with the efforts of the Cancer Moonshot to help reduce the number of cancer deaths and eventually end cancer as we know it.

Changes to the Review Timeframes for the Hospital Outpatient Department Prior Authorization Process

The Lung Association supports support CMS' decision to align Medicare fee for service prior authorization review timeframe for standard review requests for hospital outpatient department services with the timeframe in the Interoperability and Prior Authorization final rule. Prior authorization is a time-consuming process that can burden providers, divert valuable resources away from direct care, and cause delays in patient access to needed services and treatment. The Lung Association supports shortening the timelines to ensure that standard requests are resolved in 72 hours and expedited requests are resolved in 24 hours because individuals with chronic illness are frequently harmed by unnecessary delays in receiving needed treatments.[11]

Payment for Medicare Telehealth Services

The Lung Association supports access to telehealth services, especially for those living in rural areas. The flexibilities that have been in place since the beginning of the COVID-19 public health emergency have allowed individuals living with lung diseases to access critical, needed services.

The Lung Association supports the recommendation made by the American Association of Cardiovascular and Pulmonary Rehabilitation and other organizations in their comments to this MPFS recommending that "CMS finalize its proposals to allow direct supervision…for pulmonary rehabilitation services furnished in physician offices and hospital outpatient departments to be met via audio/video real-time communications technology through the end of CY 2025 at a minimum…and strongly urge CMS to make this flexibility permanent…with the goal of maintaining ongoing accessibility of these valuable services."

Merit-based Incentive Payment System (MIPS): Changes to the Improvement Activities Inventory

The Lung Association supports CMS's proposal to add a new improvement activity in the Population Management subcategory of the Merit-based Incentive Payment System (MIPS).

The activity, IA_PM_XX, titled "Implementation of Protocols and Provision of Resources to Increase Lung Cancer Screening Uptake" would allow MIPS-eligible clinicians to receive credit for establishing a process or procedure to increase rates of lung cancer screening with the goal of increasing lung cancer screening rates and improving associated outcomes. Medical providers are a trusted source for many patients and the Lung Association believes this measure will lead to an increase of high-risk patients being screened for lung cancer.

However, to truly get the benefit of the improvement activity, a lung cancer screening measure is needed. The Lung Association is currently working with the National Committee for Quality Assurance to create such a lung cancer screening measure. Once final, this measure will complement the proposed improvement activity above by showing the impact of the improvement activity.

Conclusion

The American Lung Association appreciates the opportunity to submit these comments on the CY25 Medicare Physician Fee Schedule proposed rule. Please reach out to Erika Sward, Assistant Vice President of Nationwide Advocacy at the American Lung Association at Erika.Sward@lung.org if you have any questions or would like to discuss anything further.

Sincerely,

Harold P. Wimmer
National President and CEO

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[10] State of Lung Cancer | Racial and Ethnic Disparities | American Lung Association

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