American Lung Association.

August 24, 2026

The Honorable Robert F. Kennedy Jr.
Secretary
Department of Health & Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable T. March Bell
Inspector General
Office of Inspector General
U.S. Department of Health & Human Services
330 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP [OIG-2602-N]

Dear Secretary Kennedy and Inspector General Bell:

The American Lung Association appreciates the opportunity to provide comments on the Office of Inspector General's (OIG) request for information (RFI) regarding a new safe harbor under the federal anti-kickback statute (AKS).

The American Lung Association is the nation's oldest voluntary public health organization and represents the more than 34 million people in the United States living with lung disease, including millions who rely on Medicare and Medicaid coverage. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

Clinical trials are a cornerstone of both healthcare and public health, providing patients access to new, innovative treatments and interventions and advancing understanding of how to prevent and treat disease, including lung diseases such as lung cancer, asthma, COPD and pulmonary fibrosis. Yet clinical trials often face significant challenges enrolling patients. According to a 2025 issue brief from the Department of Health and Human Services, an estimated 30% of clinical trials conducted between 2011 and 2021 were suspended or terminated after failing to reach target enrollment.[1] Research has shown that financial and logistical burdens – including travel expenses, out-of-pocket medical expenses, missed work, lost wages and childcare – are among the leading barriers that deter patients from participating in clinical trials. These barriers are particularly significant for patients who are low-income, live in rural communities, live with

serious and chronic health conditions like lung disease or face other challenges in accessing care.

Current federal fraud and abuse laws, however, discourage sponsors from directly reimbursing trial participants who receive their coverage from Medicare, Medicaid and other federal healthcare programs for trial-related expenses due to concerns that such payments could violate the AKS or beneficiary inducements civil monetary penalty (CMP) statute. **The Lung Association urges OIG to swiftly adopt a new safe harbor under the AKS for reasonable trial-related support and establish a corresponding exception under the beneficiary inducements CMP.** Providing a clear regulatory framework would address long-standing barriers to clinical trial participation, thereby enabling more meaningful access for patients who rely on federal healthcare programs, including patients with lung disease, and ultimately advance research into new treatments and interventions.

In addition to the comments submitted jointly with patient advocacy, public health and provider organizations, the American Lung Association respectfully submits the following comments.

Addressing financial and logistical barriers can improve access to clinical trials.

The Lung Association commends OIG for recognizing that "the reliability and validity of clinical trial results depends on recruiting a wide range of baseline characteristics that reflect the intended use population, as well as the continued cooperation of enrolled participants." As research has consistently shown, and as OIG notes in the RFI, the additional costs and burdens associated with trail participation often discourage people from enrolling in or remaining in clinical trials. A 2019 meta-analysis and systematic review published in the 2019 *Journal of the National Cancer Institute* found that cost concerns and logistical barriers such as transportation were among the top reasons patients declined to participate in clinical trials.[2] Commonly cited barriers include the distance to trial sites, time required to participate, competing caregiving and job responsibilities and the financial costs associated with these obligations.[3]

These barriers can be particularly consequential for people with limited financial resources, those living in rural communities and those managing serious and chronic health conditions, including lung cancer. Cancer places an already enormous financial strain on patients and families. Patients with cancer experience greater financial burden, higher out-of-pocket costs and increased risk for bankruptcy compared with patients without cancer.[4,5] Medicare beneficiaries with cancer are at high risk of financial hardship.[6] The added expenses related to clinical trial participation, including the costs of more frequent clinical visits, transportation and travel to trial sites, can further compound these financial challenges. Consistent with these concerns, one analysis of lung cancer clinical trial enrollment found that patients with Medicaid or who were uninsured, those in the lowest socioeconomic status group, those treated at community-based cancer programs, and those who lived far from cancer care facilities were the least likely to enroll.[7]

For patients with COPD and other chronic respiratory diseases, clinical trial participation may similarly require repeated visits to specialized care centers, creating significant geographic barriers for patients who live in rural communities or medically underserved areas.[8,9,10] Patients with advanced respiratory disease, including pulmonary fibrosis, may also experience additional physical barriers to travel, including breathlessness, fatigue, reduced mobility or dependence on supplemental oxygen.[11]

There is clear evidence that providing financial assistance can help alleviate these barriers and improve access to clinical trials. For example, a 2016 study found that targeted financial assistance had a positive impact on cancer clinical trial enrollment, with participants who reported greater financial barriers, lived farther from the trial site and had lower incomes able to enroll after receiving the assistance.[12] Other research similarly demonstrates that trial-related financial considerations can influence patients' willingness and ability to participate and underscore the importance of efforts to address financial and logistical barriers.[13] Providing reasonable support for trial-related expenses can help ensure that these barriers do not prevent otherwise eligible patients from accessing potentially life-saving clinical research.

Existing safe harbors and CMP exceptions are inadequate.

Existing safe harbors and exceptions to the beneficiary inducements CMP do not adequately address the financial and logistical barriers that prevent patients from participating in clinical trials. Although current law provides protection for certain forms of transportation and patient supports, these protections were not designed specifically for clinical trial participation; do not address lodging, meals, childcare, caregiver support, stipends or other trial-related burdens; and contain significant limitations. Similarly, CMP exceptions for promoting access to care or addressing financial need are subject to specific eligibility and documentation requirements and do not provide a clear pathway for sponsors to reimburse participants for legitimate, reasonable trial-related expenses. As noted in the RFI, OIG has published 10 favorable advisory opinions permitting the waiver or subsidization of certain cost-sharing obligations for clinical trial participants. OIG has not issued guidance related to transportation, childcare or stipends for clinical trial participants. The lack of a dedicated safe harbor and guidance for clinical trials creates legal uncertainty that discourages sponsors from reimbursing participants for trial-related expenses.[14]

Establish appropriate safeguards to address barriers while protecting patients.

OIG should establish appropriate safeguards for clinical trial remuneration that balance addressing financial and logistical barriers while protecting patients. A clear separation should exist between remuneration that facilitates participation in a clinical trial and remuneration that steers patients toward specific commercial items or services outside the study protocol. Any permitted financial support should align strictly with an Institutional Review Board-approved protocol; should rely on objective, consistently applied eligibility criteria available to all participants regardless of their insurance type; and should not be used to market products or services. The Lung Association supports advertising limitations to prevent remuneration from

becoming a marketing tool, while enabling clear, accurate and educational information to be provided to patients, caregivers and providers. These safeguards align with OIG's long-standing concerns about patient steering, overutilization, patient choice and program cost while preserving the ability to remove access barriers.

Conclusion

Thank you for the opportunity to comment on this important issue. The Lung Association urges OIG to establish a new safe harbor for clinical trials to address long-standing barriers and enable meaningful access to clinical trials for patients with lung disease. Recognizing that the formal rulemaking process may take multiple years, the Lung Association encourages OIG to issue guidance in the interim period to support patients' access to clinical trials.

Sincerely,

American Lung Association

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[1] U.S. Dep't of Health & Human Servs., Office of the Assistant Secretary for Planning & Evaluation (ASPE), Empowering Patients to Participate in Clinical Trials (July 2025), https://aspe.hhs.gov/reports/participate-clinical-trials.

[2] Unger, J. M., Vaidya, R., Hershman, D. L., Minasian, L. M., & Fleury, M. E. (2019). Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation. *Journal of the National Cancer Institute*, *111*(3), 245–255. https://doi.org/10.1093/jnci/djy221

[3] Thakur, N., Lovinsky-Desir, S., Appell, D., Bime, C., Castro, L., Celedón, J. C., Ferreira, J., George, M., Mageto, Y., Mainous III, A. G., Pakhale, S., Riekert, K. A., Roman, J., Ruvalcaba, E., Sharma, S., Shete, P., Wisnivesky, J. P., & Holguin, F. (2021). Enhancing Recruitment and Retention of Minority Populations for Clinical Research in Pulmonary, Critical Care, and Sleep Medicine: An Official American Thoracic Society Research Statement. *American journal of respiratory and critical care medicine*, *204*(3), e26–e50. https://doi.org/10.1164/rccm.202105-1210ST

[4] Bernard, D. S., Farr, S. L., & Fang, Z. (2011). National estimates of out-of-pocket health care expenditure burdens among nonelderly adults with cancer: 2001 to 2008. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*, *29*(20), 2821–2826. https://doi.org/10.1200/JCO.2010.33.0522

[5] Ramsey, S., Blough, D., Kirchhoff, A., Kreizenbeck, K., Fedorenko, C., Snell, K., Newcomb, P., Hollingworth, W., & Overstreet, K. (2013). Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health affairs (Project Hope)*, *32*(6), 1143–1152. https://doi.org/10.1377/hlthaff.2012.1263

[6] Narang, A. K., & Nicholas, L. H. (2017). Out-of-Pocket Spending and Financial Burden Among Medicare Beneficiaries With Cancer. *JAMA oncology*, *3*(6), 757–765. https://doi.org/10.1001/jamaoncol.2016.4865

[7] Kwak, M., Bassiri, A., Jiang, B., Sinopoli, J., Tapias-Vargas, L., Linden, P. A., & Towe, C. W. (2024). National enrollment of lung cancer clinical trials is disproportionate based on race and health care access. *The Journal of thoracic and cardiovascular surgery*, *168*(4), 1235–1242. https://doi.org/10.1016/j.jtcvs.2023.12.012

[8] Thornton, M. E., Mannino, D. M., Ohar, J. A., Putcha, N., Simonelli, P. F., Dransfield, M. T., & Drummond, M. B. (2025). Improving Research for COPD in Rural Areas: A Statement from the COPD Foundation Medical and Scientific Advisory Committee. *Chronic obstructive pulmonary diseases (Miami, Fla.)*, *12*(5), 419–425. https://doi.org/10.15326/jcopdf.2025.0618

[9] Huang, B., De Vore, D., Chirinos, C., Wolf, J., Low, D., Willard-Grace, R., Tsao, S., Garvey, C., Donesky, D., Su, G., & Thom, D. H. (2019). Strategies for recruitment and retention of underrepresented

populations with chronic obstructive pulmonary disease for a clinical trial. *BMC medical research methodology*, *19*(1), 39. https://doi.org/10.1186/s12874-019-0679-y
[10] Boente, R. D., Schacht, S., Borton, R., Vincent, J., Golzarri-Arroyo, L., & Rattray, N. (2024). Assessing the acceptability and feasibility of remote spirometric monitoring for rural patients with interstitial lung disease: a multimethod approach. *Respiratory research*, *25*(1), 92. https://doi.org/10.1186/s12931-024-02735-z
[11] Jones, S., Flewett, M., Flewett, R., Lee, S., Vick, B., Thompson, M., Pinnetti, S., Zoz, D. F., Hoffmann-Vold, A. M., Kreuter, M., & Maher, T. M. (2023). Clinical trial simulations in pulmonary fibrosis: patient-focused insights and adaptations. *ERJ open research*, *9*(3), 00602-2022. https://doi.org/10.1183/23120541.00602-2022
[12] Nipp, R. D., Lee, H., Powell, E., Birrer, N. E., Poles, E., Finkelstein, D., Winkfield, K., Percac-Lima, S., Chabner, B., & Moy, B. (2016). Financial Burden of Cancer Clinical Trial Participation and the Impact of a Cancer Care Equity Program. *The oncologist*, *21*(4), 467–474. https://doi.org/10.1634/theoncologist.2015-0481
[13] Williams, C. P., Reh, N., Chen, M., Henderson, N., Caston, N. E., Rocque, G. B., & Gutnik, L. (2025). Clinical trial-related financial considerations from Deep South-patients with breast cancer who previously declined trial participation. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer*, *33*(9), 771. https://doi.org/10.1007/s00520-025-09823-w
[14] Largent, E. A., Heffernan, K. G., Joffe, S., & Lynch, H. F. (2020). Paying Clinical Trial Participants: Legal Risks and Mitigation Strategies. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*, *38*(6), 532–537. https://doi.org/10.1200/JCO.19.00250