NATIONAL HEALTH COUNCIL

August 24, 2026

The Honorable T. March Bell
Inspector General
Office of Inspector General
Department of Health and Human Services
Cohen Building
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; RIN 0936-AA16]

Submitted electronically via regulations.gov

Dear Inspector General Bell:

The National Health Council (NHC) appreciates the opportunity to provide comments in response to the Department of Health and Human Services Office of Inspector General's (OIG's) request for information (RFI) regarding the application of the Federal anti-kickback statute (AKS) and the Beneficiary Inducements Civil Monetary Penalty (CMP) to remuneration provided in connection with clinical trial participation.

The NHC unites nearly 200 national organizations—including leading patient groups, research institutions, providers, caregivers, and businesses across the health care sector—to drive patient-centered health policy. Representing 200+ million Americans with chronic diseases and disabilities, the NHC strengthens its members' collective influence to expand access to quality, affordable, and equitable health care. The NHC fosters collaboration to shape policies that reflect the needs of patients.

The NHC welcomes OIG's attention to the financial and practical barriers that can prevent patients from enrolling in and remaining in clinical trials. Although discussions of clinical-trial access often appropriately focus on eligibility criteria, site availability, awareness, trust, and protocol design, participation also depends on whether patients and their family can manage the costs, time demands, and disruption associated with research. Even when the investigational product and protocol-required services are provided without charge, participants may face significant expenses related to transportation, parking, lodging, meals, childcare or other dependent care, technology, and caregiver support. Time away from employment, education, treatment, and other responsibilities can impose additional burdens that are difficult to quantify but no less consequential. These barriers are especially important for people living with chronic diseases, disabilities, rare conditions, cancer, and other serious illnesses; people who live far from specialized research sites; individuals with limited or inflexible paid leave;

and participants who require accessible transportation, accommodations, or assistance from a caregiver or support person.[1,2,3,4]

The NHC has long supported policies that reduce avoidable barriers to clinical-trial participation. These policies can also help ensure that research evidence reflects the populations that will ultimately use the products being studied. From the patient perspective, reimbursement and compensation are not peripheral administrative matters because they can determine whether an otherwise eligible individual can participate, whether a caregiver can accompany them, or whether a family must choose between contributing to research and meeting ordinary household obligations. At the same time, these arrangements must be transparent and appropriately structured to preserve informed and voluntary participation. Consistent with its prior comments regarding the Federal anti-kickback statute (AKS), safe harbors, and the Beneficiary Inducements Civil Monetary Penalty (CMP), the NHC supports greater clarity and flexibility when such changes can improve patient access. Any resulting framework should include appropriate oversight, meaningful patient safeguards, and clear expectations for the sponsors, research sites, nonprofit organizations, patient organizations, vendors, and other stakeholders that may fund or administer participant support.[5,6,7]

The NHC also recognizes that the bipartisan Clinical Trial Modernization Act addresses several of the same barriers through proposed statutory protections for specified clinical-trial expenses, necessary digital health technologies, and qualifying payments of participant cost-sharing obligations. OIG's work should complement those legislative efforts without duplicating or inadvertently narrow by them. While Congress considers the legislation, OIG can clarify how the current law applies and address issues that the

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[1] Silke Schoch, "Patients, Poverty, and Participation in Research: The Hidden Costs of Disease and Socioeconomic Status," National Health Council, January 30, 2023, https://nationalhealthcouncil.org/blog/patients-poverty-and-participation-in-research-the-hidden-costs-of-disease-and-socioeconomic-status/.

[2] National Health Council, "Comments on FDA's Draft Guidance on Enhancing the Diversity of Clinical Trial Populations," August 6, 2019, 4–5, https://nationalhealthcouncil.org/wp-content/uploads/2019/12/NHC_Comments_FDA_Clinical_Trial_Eligibility.pdf.

[3] Barbara E. Bierer et al., *Toward a National Action Plan for Achieving Diversity in Clinical Trials* (Milken Institute, May 2024), 15–17, https://ctti-clinicaltrials.org/wp-content/uploads/2024/05/Toward-a-National-Action-Plan-for-Achieving-Diversity-Clinical-Trials-240502_FINAL.pdf.

[4] Grace Jo et al., "Equitable Inclusion of People with Disabilities in Clinical Trials: A Scoping Review," *BMJ Open* 16, no. 2 (2026): e108550, https://doi.org/10.1136/bmjopen-2025-108550.

[5] National Health Council, "Comments on FDA's Draft Guidance," 2–5.

[6] National Health Council, "Comments on Decentralized Clinical Trials for Drugs, Biological Products, and Devices," August 1, 2023, 1–3, https://nationalhealthcouncil.org/wp-content/uploads/2023/08/Decentralized-Trials-Guidance-Comments.pdf.

[7] National Health Council, "Comments on Landmark FDA Guidance for Diversity in Clinical Trials," September 26, 2024, https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-landmark-fda-guidance-for-diversity-in-clinical-trials/.

legislation may not fully resolve. These include compensation for participants' time and burden; support for caregivers and dependent care, workable reimbursement methods; the role of Institutional Review Boards (IRBs); and the treatment of remuneration when participation ends before a study is complete. A coordinated approach is particularly important because patients and research stakeholders should not have to navigate materially different standards depending on whether a particular form of support is addressed through statute, regulation, guidance, or an advisory opinion.[8,9,10]

Summary of Recommendations

The NHC recommends that OIG:

- Develop a coordinated framework that complements the Clinical Trial Modernization Act and provides appropriate clarity for reasonable clinical-trial expense reimbursement, compensation for participants' time and burden, necessary technology, cost-sharing assistance, and related forms of participant support;
- Distinguish among reimbursement of expenses, compensation for time and burden, and additional milestone or completion payments, rather than applying the same conditions to forms of remuneration that serve different purposes and present different considerations;
- Preserve flexibility by avoiding rigid national dollar caps, general financial-need requirements, categorical exclusions based on sponsor or trial type, and reimbursement processes that routinely require participants to pay substantial costs upfront or satisfy documentation requirements disproportionate to the amount being reimbursed;
- Recognize that support may appropriately be funded or administered by a range of research stakeholders, including sponsors, research sites, academic institutions, nonprofit organizations, patient organizations, foundations, and qualified third-party vendors, subject to clear and consistently applicable standards;
- Require clear disclosure through the informed-consent process, appropriate review of payment structures and recruitment communications, and reimbursement of expenses incurred and payment of compensation if participation ends early; and

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[8] National Health Council, "FDA Tackles Clinical Trial Diversity—Is Congress Next?," August 29, 2024, https://nationalhealthcouncil.org/blog/fda-tackles-clinical-trial-diversity-is-congress-next/.

[9] Clinical Trial Modernization Act of 2026, discussion draft, https://www.warner.senate.gov/wp-content/uploads/2026/05/KEN26219.pdf.

[10] Department of Health and Human Services, Office of Inspector General, "Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP," *Federal Register*, June 24, 2026, https://www.federalregister.gov/documents/2026/06/24/2026-12676/medicare-and-state-health-care-programs-fraud-and-abuse-request-for-information-regarding-the.

- Pair any safe harbor or CMP protection with practical guidance and ongoing engagement with patients, caregivers, patient organizations, sponsors, sites, IRBs, and other stakeholders to assess whether participant support is accessible and workable in practice.

Clinical-Trial Support Should Be Evaluated Based on Whether It Reduces Barriers in Practice

The NHC agrees with OIG that appropriate remuneration can facilitate clinical-trial participation among Federal health care program enrollees, but the practical value of that support depends on more than the categories of expenses that are nominally eligible for reimbursement. A participant in a short study conducted at a nearby community site may face only modest transportation and parking costs, while a participant in a rare-disease, oncology, or other specialized trial may need to travel across state lines, remain near a research center for several days, bring a caregiver or support person, and arrange care for children or other family members. Participants with disabilities may require accessible transportation, specialized lodging, personal assistance, or other accommodations that cost more than standard options, and people living in rural areas may face longer travel distances, fewer transportation choices, and limited access to nearby study sites. These underscore the need for flexible approaches to participant support that account for varying costs and logistical demands across studies and participant populations.[11,12,13]

For that reason, OIG's framework should look beyond whether reimbursement is authorized and consider whether reimbursement processes are timely, predictable, understandable, and workable for participants who may be unable to cover substantial upfront costs while awaiting repayment. Direct booking or payment by a sponsor, site, or vendor; reasonable advances; mileage or per diem methodologies; payment cards; and reimbursement based on receipts, attestations, or other documentation proportionate to the expense may each be appropriate depending on the study and participant population. The NHC encourages OIG to preserve this operational flexibility and to avoid requirements that appear administratively neutral but, in practice, shift the

[11] Ryan D. Nipp et al., "Addressing the Financial Burden of Cancer Clinical Trial Participation: Longitudinal Effects of an Equity Intervention," *The Oncologist* 24, no. 8 (2019): 1048–55, https://doi.org/10.1634/theoncologist.2019-0146.

[12] Christopher P. Williams et al., "Influence of Cost-Related Considerations on Clinical Trial Participation: Results from the 2020 Health Information National Trends Survey (HINTS)," *Journal of General Internal Medicine* 38, no. 5 (2023): 1200–1206, https://doi.org/10.1007/s11606-022-07801-0.

[13] Allison Kolbe and Agata Bodie, *Financial Stress Associated with Oncology Clinical Trial Participation* (Office of the Assistant Secretary for Planning and Evaluation, January 16, 2025), https://aspe.hhs.gov/reports/financial-stress-clinical-trial.

financial burden back to patients and caregivers or make support particularly difficult to access for participants least able to absorb those costs.[14,15,16]

Expense reimbursement should generally be available without requiring participants to demonstrate financial need because these costs arise from participation in a research study. Means testing would require collection of sensitive financial information, create administrative complexity and potential stigma, and result in unequal access to reimbursement among participants who incur comparable research-related expenses. Similarly, participants should not be required to contribute a percentage of the cost of travel, technology, lodging, or other support intended to make participation feasible. The NHC previously expressed concern that mandatory patient contributions within safe-harbor arrangements could exclude individuals of limited means from the very opportunities the protection was intended to facilitate, and that principle applies with particular force when the costs at issue are created by the design and location of the research.[17,18,19]

Reimbursement for Expenses and Compensation for Time and Burden Warrant Distinct Treatment

The NHC encourages OIG to distinguish reimbursement for participation-related expenses from compensation for participants' time, inconvenience, and contribution to research. Both can help make participation feasible for patients, but OIG should evaluate them according to their distinct purposes rather than assume the same conditions are appropriate for both. Reimbursement restores costs that an individual or family incurs because of the trial, which may include transportation, airfare, mileage, tolls, parking, lodging, meals, childcare, eldercare, care for another dependent, expenses incurred by an accompanying caregiver or support person, accessibility-related services, and technology or connectivity needed to complete study activities.

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[14] Barbara E. Bierer et al., "Fair Payment and Just Benefits to Enhance Diversity in Clinical Research," *Journal of Clinical and Translational Science* 5, no. 1 (2021): e159, https://doi.org/10.1017/cts.2021.816.

[15] Barbara E. Bierer et al., *Toward a National Action Plan for Achieving Diversity in Clinical Trials*, 15–17.

[16] PAN Foundation, *Optimizing Clinical Trial Participation: Addressing Social and Financial Factors*, February 2026, https://clinicaltrials.panfoundation.org/reports/report-key-solutions-to-expand-participation-in-clinical-trials/.

[17] National Health Council, "Comments on OIG Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP," December 31, 2019, https://nationalhealthcouncil.org/wp-content/uploads/2019/12/NHC-Comments-on-OIG-Safe-Harbor.pdf.

[18] Secretary's Advisory Committee on Human Research Protections, "Addressing Ethical Concerns Regarding Offers of Payment to Research Participants," September 30, 2019, https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-september-30-2019/index.html.

[19] Allison Kolbe and Agata Bodie, *Use of Participant Compensation in U.S. Clinical Research Studies* (Office of the Assistant Secretary for Planning and Evaluation, July 30, 2025), https://aspe.hhs.gov/reports/compensation-clinical-research.

OIG may reasonably require expenses to be verified, but the method should reflect how those expenses are actually incurred. Standard mileage rates, reasonable per diem amounts, direct booking, local cost schedules, and participant attestations can provide accountability without requiring an itemized receipt for every meal, mile, or informal caregiving arrangement.[20,21]

Compensation serves the related but distinct purpose of recognizing the time and burden associated with trial participation. Participants and caregivers contribute time, information, and lived experience that are essential to the research enterprise. For example, patients may travel to and attend in-person studies, complete questionnaires and diaries, use of digital tools, provide biological samples, participate in interviews, undergo invasive or inconvenient procedures, and complete long-term follow-up activities. Enrollment in Medicare, Medicaid, or another Federal health care program should not, by itself, preclude compensation for those contributions. Compensation methodologies should be transparent and reasonably connected to the expected time and burden. Compensation should not be presented as a therapeutic benefit or tied to a particular outcome, and participants should understand what they will receive for the activities they complete.[22,23,24]

Milestone, retention, or completion payments may warrant additional scrutiny when a substantial portion of a participant's total payment is withheld until the end of a study or when the amount bears little relationship to that participants' expenses, time, or burden. However, categorically excluding these payments would be unnecessarily rigid. A reasonable milestone payment may recognize the additional burden of completing long-term follow-up or a particularly demanding phase of a protocol. The more appropriate inquiry is whether the amount and timing are reasonable, transparently disclosed, reviewed through the applicable research-oversight process, and structured so that participants remain free to withdraw. Participants who withdraw, lose eligibility, experience an adverse event, or are removed from a study should receive reimbursement for eligible expenses already incurred and compensation for activities

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[20] SACHRP, "Addressing Ethical Concerns Regarding Offers of Payment."

[21] Drug Information Association, "Breaking Financial Barriers: Making the Shift to Reasonable Compensation for Clinical Trial Participants," *Global Forum*, December 2024, https://globalforum.diaglobal.org/issue/december-2024/breaking-financial-barriers-making-the-shift-to-reasonable-compensation-for-clinical-trial-participants/.

[22] Barbara E. Bierer et al., "Fair Payment and Just Benefits to Enhance Diversity" (2021).

[23] SACHRP, "Addressing Ethical Concerns Regarding Offers of Payment."

[24] U.S. Food and Drug Administration, "Payment and Reimbursement to Research Subjects," July 12, 2018, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects.

already completed, rather than forfeiting amounts already owed to them because participation ended before the study's conclusion.[25,26]

A Coordinated and Flexible Framework Would Better Support Patients and Research Stakeholders

The Clinical Trial Modernization Act would resolve several important issues through statutory protections, and the NHC encourages OIG to structure any regulatory or subregulatory action so that it can operate coherently alongside those protections and does not create a narrowed or conflicting set of conditions. Because the legislation has not yet been enacted, OIG nevertheless has a meaningful role under current law. The bill does not fully address several issues RFI: stipends or compensation for time and burden; childcare and other dependent-care costs; lodging; milestone payments; advertising; payment following withdrawal; and the range of entities that may administer assistance. OIG could provide interim clarity through guidance while considering whether a clinical-trial-specific AKS safe harbor and corresponding CMP protection are warranted and could revisit that guidance following enactment of legislation to ensure a consistent Federal approach.[27,28]

Any framework should accommodate the range of entities involved in clinical research rather than limiting protection to government-funded studies or presuming that support funded by a particular type of sponsor is inappropriate. Industry-sponsored studies play a central role in the development and evaluation of drugs, biologics, devices, diagnostics, and other medical products, and participants in those studies experience the same transportation, lodging, childcare, employment, and caregiving burdens as participants in government- or nonprofit-funded research. Research sites may not have the infrastructure to arrange complex travel or administer timely reimbursement across a multisite study. Sponsors or specialized vendors may offer additional capacity to provide advances, book accessible transportation and lodging, and apply consistent payment processes. Patient organizations and nonprofit entities may also bring important knowledge of the practical needs of people living with particular diseases, disabilities, or rare conditions. Clear, consistently applicable standards would give these

[25] International Council for Harmonisation, E6(R3) Good Clinical Practice: Guidance for Industry (U.S. Food and Drug Administration, September 2025), secs. 1.2.8–1.2.9, https://www.fda.gov/media/169090/download.

[26] FDA, "Payment and Reimbursement to Research Subjects."

[27] Clinical Trial Modernization Act of 2026, discussion draft.

[28] Department of Health and Human Services, OIG, "Medicare and State Health Care Programs," *Federal Register*, June 24, 2026.

stakeholders greater certainty without requiring participant support to be administered by a single type of entity or through a single model.[29,30,31]

Those standards should preserve an appropriate boundary between participant support and unrelated health care or commercial decisions without approaching sponsor involvement as inherently suspect. Remuneration should not be conditioned on future use of the studied product, purchase of another product or service, selection of an unrelated provider or supplier, achievement of a particular clinical outcome, or agreement to receive unrelated promotional communications. Information collected to administer reimbursement should be limited to what is reasonably necessary for the research and payment processes and handled in accordance with applicable privacy requirements. These conditions reflect the basic purpose of a patient-centered framework: to allow legitimate support that makes participation possible while maintaining informed choice and clear expectations for all parties.[32,33,34]

Transparency and Oversight Should Protect Participants Without Recreating Administrative Barriers

Institutional Review Board (IRB) oversight is an important component of a broader framework. IRBs help protect the rights and welfare of research participants by reviewing informed-consent materials, recruitment practices, and payment structures. As part of that review, they consider whether payment is appropriately prorated, whether participants understand what will happen if they withdraw, and whether recruitment communications present remuneration accurately and in appropriate proportion to the study's risks, potential benefits, alternatives, and expected burden. At the same time, IRBs are principally responsible for protecting research participants, not interpreting Federal fraud-and-abuse law. Their review should not substitute for clear Federal standards under the AKS and Beneficiary Inducements CMP. OIG should therefore establish baseline conditions on which IRBs, sponsors, sites, nonprofit organizations, and vendors can rely, while recognizing IRB review as one meaningful

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[29] National Health Council, "Comments on Decentralized Clinical Trials."

[30] Demi L. MacLennan et al., "Clinical Trial Site Perspectives and Practices on Study Participant Diversity and Inclusion," *Clinical Pharmacology & Therapeutics* 113, no. 3 (2023): 670–79, https://doi.org/10.1002/cpt.2817.

[31] Barbara E. Bierer et al., *Toward a National Action Plan for Achieving Diversity in Clinical Trials*, 10–17, 21–23.

[32] National Health Council, "Comments on OIG Revisions."

[33] Clinical Trial Modernization Act of 2026, discussion draft.

[34] Department of Health and Human Services, OIG, "Medicare and State Health Care Programs," *Federal Register*, June 24, 2026.

safeguard rather than the sole determinant of whether an arrangement is protected.[35,36,37]

Participants should receive clear and understandable information about the nature and amount of reimbursement or compensation, the method used to calculate it, when payment will be made, which expenses are eligible, what documentation is required, and what happens if their participation ends early. Recruitment materials should be permitted to state accurately that reimbursement or compensation is available because this support may determine whether a person can realistically participate. Payment, however, should not be characterized as a clinical benefit or presented in a manner that overshadows other material information about the study. Where a specific amount is advertised, the communication should clarify whether it is a maximum amount, whether it depends on completing particular visits or activities, and whether expense reimbursement is separate from compensation for time and burden. These disclosure principles should apply across websites, social media, trial-matching platforms, patient-organization communications, and other recruitment channels, with coordination among OIG, FDA, and other relevant agencies to avoid conflicting expectations.[38,39,40,41]

Implementation Should Be Measured by Its Effect on Real-World Access

The value of any safe harbor, CMP exception, or guidance will ultimately depend on whether stakeholders can apply it consistently and whether patients and caregivers receive meaningful support in practice. OIG should continue engaging patients, caregivers, patient organizations, research sponsors, sites, investigators, IRBs, nonprofit organizations, vendors, and compliance professionals as it develops and implements any policy. Those with direct experience participating in or supporting

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[35] U.S. Food and Drug Administration, “Institutional Review Boards Frequently Asked Questions: Guidance for Institutional Review Boards and Clinical Investigators,” February 2025, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/institutional-review-boards-frequently-asked-questions.

[36] ICH, E6(R3) Good Clinical Practice, secs. 1.2.8–1.2.9.

[37] FDA, “Payment and Reimbursement to Research Subjects.”

[38] U.S. Department of Health and Human Services, Office for Human Research Protections, “Informed Consent FAQs,” accessed August 6, 2026, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html.

[39] FDA, “Payment and Reimbursement to Research Subjects.”

[40] National Health Council, “Comments on ClinicalTrials.gov Modernization,” March 13, 2020, https://nationalhealthcouncil.org/wp-content/uploads/2020/03/NLM-ClinicalTrials.gov-Modernization-Comments-Final.pdf.

[41] National Health Council, “Comments on Key Information and Facilitating Understanding in Informed Consent,” April 30, 2024, https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-key-information-and-facilitating-understanding-in-informed-consent/.

clinical trials can help identify when a safeguard protects informed choice and when an administrative requirement unintentionally becomes another barrier.[42,43,44]

OIG should also remain attentive to whether uncertainty under the AKS or Beneficiary Inducements CMP results in Federal health care program enrollees receiving different or more limited support than other participants, whether participants are routinely required to advance costs that they cannot reasonably absorb, whether disability- and caregiver-related expenses are accommodated, and whether requirements are interpreted inconsistently across sponsors and sites. This evaluation need not require extensive reporting from every trial or create new obligations for participants. Instead, OIG could draw on stakeholder feedback, advisory-opinion requests, compliance inquiries, targeted reviews, and coordination with FDA, the National Institutes of Health, the Centers for Medicare & Medicaid Services, and other relevant agencies. Where implementation reveals recurring uncertainty or unintended access barriers, the NHC encourages OIG to revisit its regulations or guidance so that the framework remains responsive to evolving trial designs, technologies, participant needs, and related Federal law.[45,46,47]

Conclusion

The NHC appreciates OIG's attention to the financial and practical barriers associated with clinical-trial participation. Patients and caregivers contribute indispensable time, experience, data, and expertise to medical research, and a patient-centered research system should not require them to absorb unreasonable expenses or substantial uncompensated burdens as the price of participation. The NHC supports the objectives of the Clinical Trial Modernization Act and encourages OIG to use its existing authority to complement those legislative efforts, provide appropriate clarity under current law,

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[42] National Health Council, "Comments on Landmark FDA Guidance for Diversity in Clinical Trials," September 26, 2024, https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-landmark-fda-guidance-for-diversity-in-clinical-trials/.

[43] PAN Foundation, *Optimizing Clinical Trial Participation*.

[44] Allison Kolbe and Agata Bodie, *Empowering Patients to Participate in Clinical Trials* (Office of the Assistant Secretary for Planning and Evaluation, July 2, 2025), https://aspe.hhs.gov/reports/participate-clinical-trials.

[45] Department of Health and Human Services, OIG, "Medicare and State Health Care Programs.

[46] Kolbe and Bodie, *Empowering Patients to Participate*.

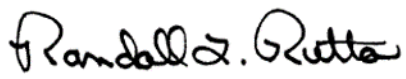
[47] MacLennan et al., "Clinical Trial Site Perspectives," 670–79.

and address forms of participant support that may not be fully resolved through legislation.[48,49,50]

A coordinated and flexible framework should distinguish expense reimbursement from compensation for time and burden, accommodate the range of stakeholders involved in research, and pair clear standards with transparency and appropriate oversight. Such a framework can give patients a more realistic opportunity to participate and provide while sponsors, sites, nonprofit organizations, patient organizations, and other stakeholders with greater certainty. The ultimate measure of this effort will be whether eligible individuals can make informed choices about research participation without financial and logistical barriers effectively making the decision for them.[51,52,53]

Thank you for the opportunity to provide comments on this RFI. Please do not hesitate to contact Kimberly Beer, Senior Vice President, Policy & External Affairs, at kbeer@nhcouncil.org, or Shion Chang, Assistant Vice President, Policy & Regulatory Affairs, at schang@nhcouncil.org, if you or your staff would like to discuss these comments in greater detail.

Sincerely,



Randall L. Rutta
Chief Executive Officer

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[48] Silke Schoch, “Patients, Poverty, and Participation in Research.”

[49] National Health Council, “Comments on FDA’s Draft Guidance on Enhancing the Diversity of Clinical Trial Populations,” August 6, 2019.

[50] Bierer et al., *Toward a National Action Plan*.

[51] National Health Council, “Comments on OIG Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP,” December 31, 2019.

[52] National Health Council, “Comments on Landmark FDA Guidance for Diversity in Clinical Trials,” September 26, 2024.

[53] National Health Council, “Comments on Decentralized Clinical Trials for Drugs, Biological Products, and Devices,” August 1, 2023.