AdvaMed
Advanced Medical Technology Association

August 24, 2026

By Electronic Submission via www.regulations.gov

Honorable Thomas March Bell
Office of Inspector General
Department of Health and Human Services
Attention: OIG-2602-N
330 Independence Avenue, SW
Washington, DC 20201

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

Dear Mr. Bell:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to respond to the Request for Information (RFI) included in the Proposed Rule titled, "Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Federal Anti-Kickback Statute and Beneficiary Inducements CMP," published by the Office of Inspector General of the Department of Health and Human Services (OIG) at 91 Fed. Reg. 37902 (June 24, 2026).

I. AdvaMed

AdvaMed is a trade association representing the world's leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing and life-saving health care technology purchased annually in the United States and globally. AdvaMed members range from the largest to the smallest medical technology (medtech) producers and include hundreds of small companies with fewer than 20 employees. Our members are committed to the development of new technologies and services that allow patients to lead longer, healthier, and more productive lives. The devices made by AdvaMed members help patients stay healthier longer and recover more quickly after treatment and enable clinicians to detect disease earlier and treat patients as effectively and efficiently as possible.

II. Responses to RFI Questions

A. Remuneration's Effect on Clinical Trial Participation

Please explain whether offering Federal health care program enrollees remuneration facilitates clinical trial participation and the specific factors that make such remuneration either effective or ineffective at facilitating participation.

AdvaMed Response: Clinical research depends on recruiting and retaining enough participants to generate reliable evidence and enroll study populations representative of the intended use population. Yet longstanding, well-recognized barriers impede participation. Reasonable remuneration plays an important role in facilitating prompt recruitment and sustainable retention. Reimbursement or prepaid cards or vouchers for lunch or travel to and from study facilities (including parking and tolls), for example, can help patients participate and sponsors meet recruitment timelines. Such remuneration is particularly appropriate when participants incur personal costs to enroll in a study.

Appropriate remuneration can also improve the representativeness of clinical trial populations and thereby produce generalizable clinical data. It can reduce financial barriers that disproportionately affect Medicare and Medicaid beneficiaries, many of whom are on fixed incomes, and facilitate research involving small or limited disease-state populations where recruiting and retaining enough participants is particularly challenging.

Remuneration can reduce financial barriers to enrollment and retention, particularly in multiyear studies requiring multiple visits or long-term follow-up. For example, FDA may require follow-up for several years for some novel devices, during which time trial participants may live in a location far from a trial site. By enabling participation from a broader and more representative patient population, remuneration also supports the collection of robust reimbursement and health economic data. It enhances the integrity of studies by reducing participant dropout caused by out-of-pocket costs rather than study-related factors.

These barriers are especially acute for populations that are often underrepresented in clinical research. For example, individuals living in rural communities frequently must travel significant distances to reach clinical trial sites, and the associated costs can be prohibitive. Similarly, participants with limited means may need to miss nearly a day of work when dependent on public transportation, whereas prepaid rideshare or similar transportation support may make participation feasible. Remuneration that offsets these costs, together with support for lost wages resulting from time away from work and assistance with caregiving responsibilities for children, aging family members, or participants who cannot travel independently, can make participation feasible for individuals who would otherwise be unable to enroll.

The effectiveness of remuneration in facilitating participation depends on several factors. Remuneration is more likely to be effective when the amount reasonably reflects participants' actual expenses and burdens; payments are timely, predictable, easy to access, and simple for sites to administer; remuneration is tailored to the specific barriers faced by the target patient population and research site location; and participants clearly understand the terms on which remuneration is provided. When effective, remuneration can lead to more trials being representative of the target populations for which the product under study is intended, improve retention in longer-term studies, strengthen the efficiency, quality, and competitiveness of the U.S. clinical research ecosystem, and ultimately improve health outcomes for more of the U.S. population.

B. AKS and Beneficiary Inducements CMP as Barriers to Participation

Please explain whether you view the Federal anti-kickback statute or the Beneficiary Inducements CMP as barriers to offering and providing appropriate remuneration to clinical trial participants and if so, why. In

your answer, please describe any other identified barriers to offering and providing appropriate compensation/remuneration to clinical trial participants and how those barriers relate to any barriers created by the Federal anti-kickback statute and Beneficiary Inducements CMP.

AdvaMed Response: The Federal anti-kickback statute (AKS) creates uncertainty for sponsors seeking to provide appropriate remuneration to clinical trial participants because the statute was written to address arrangements involving reimbursable health care items and services in the commercial marketplace, rather than participation in bona fide clinical research. Although remuneration provided to clinical trial participants is intended to reduce financial and logistical barriers to participation and compensate participants for research-related burdens, sponsors may be concerned that such remuneration could be viewed as inducing the receipt of items or services reimbursable by Federal health care programs, particularly in studies involving FDA-approved products.

This uncertainty is especially pronounced in post-market clinical studies, where participants may already receive a commercially available product as part of routine clinical care while participating in research that requires additional protocol-specific visits, testing, data collection, or remote monitoring. Limited guidance distinguishes remuneration intended to facilitate research participation from remuneration that could be perceived as influencing the selection of a provider, supplier, or federally reimbursable item or service.

The AKS also creates uncertainty with respect to arrangements between sponsors and research sites, because existing safe harbors do not clearly address compensation for bona fide patient identification, recruitment, or referral activities conducted pursuant to an IRB-approved clinical trial protocol; as a result, sponsors and research sites may be reluctant to pursue arrangements that could facilitate patient awareness of, and access to, clinical trial opportunities, even when undertaken for legitimate clinical research purposes and appropriate safeguards are in place.

Additional guidance or a clinical trial-specific safe harbor would provide greater certainty that remuneration reasonably related to study participation does not present the type of fraud and abuse risk the AKS was intended to prevent, provided appropriate safeguards are maintained.

The Beneficiary Inducements CMP presents a related barrier because its exceptions appear to have been developed primarily for commercial health care settings rather than clinical research. Limitations such as the financial hardship exception may be appropriate when a patient receives a commercially available product or service, but they can create barriers in the clinical trial context, where participants often assume additional burdens without a guaranteed direct clinical benefit.

OIG has issued several favorable advisory opinions addressing related remuneration arrangements in recent years. Because those opinions bind only the requesting parties, however, uncertainty remains throughout the industry for similarly situated sponsors and trial sites that have not sought their own opinions. Greater clarity regarding permissible forms of participant support, together with flexibility to address participation-related burdens, would help resolve these concerns.

C. Useful Categories and Levels of Remuneration

Please explain what categories of remuneration (including, for example, reimbursement for actual incurred expenses such as travel, lodging, parking, childcare, and meals; stipends; compensation for a participant's time; incentives to encourage enrolling in and completing the trial) and at what levels those categories of remuneration are useful to facilitate participation in clinical trials and why. Similarly, please explain what categories of remuneration are not useful to facilitate clinical trial participation. Please explain the extent to which such categories of remuneration already are offered to clinical trial participants. Please explain whether there are categories of remuneration that may be subject to heightened risks of fraud and abuse. To the extent that there is more uncertainty regarding how the Federal anti-kickback statute and Beneficiary Inducements CMP would apply to certain categories of remuneration, please explain.

AdvaMed Response: Several categories of remuneration can facilitate clinical trial participation. As noted above, reimbursement for travel, transportation, lodging, and meals associated with study-related or protocol-required activities can help sponsors and sites meet recruitment timelines by offsetting costs participants would otherwise bear. Some trials may warrant support for participants facing insurance coverage or cost-sharing gaps, including those whose private insurance denies coverage for study-related items or services, who are uninsured, or who need assistance with deductibles, copayments, or coinsurance. Data suggests that these types of cost-sharing obligations may pose some of the most significant barriers to participation, especially for trials involving procedures or other high-cost interventions.[1]

Reasonable compensation for the time, effort, inconvenience, and protocol-required activities associated with participation can also be useful, particularly when those burdens exceed those associated with standard clinical care. Some current or prospective participants may also benefit from assistance with childcare, elder care, or caregiver travel and related costs when the participant cannot travel independently.

Per-visit lump-sum stipends, pre-loaded expense cards, and other efficient payment mechanisms may also be effective and participant-friendly approaches for some trials. They recognize the time and effort required to participate while helping offset incidental expenses associated with study visits. In long-term studies with multiple follow-up visits, these approaches can improve participant retention and reduce barriers to continued participation without the administrative burden of a financial hardship program or receipt-by-receipt reimbursement process.

For certain studies, such as early feasibility, first-in-human, rare disease, or other invasive clinical trials, participants may need to travel significant distances, including nationally, to specialized study centers. Reimbursement for airfare, hotel accommodations, meals, and similar expenses may therefore be essential to enable participation and support trial access. Internet or Wi-Fi reimbursement may be similarly useful when connectivity is required for remote monitoring, telehealth visits, electronic patient-

[1] *See, e.g.*, Courtney P. Williams et al., Understanding the Financial Cost of Cancer Clinical Trial Participation, Cancer Medicine (2024), https://onlinelibrary.wiley.com/doi/epdf/10.1002/cam4.7185 (noting that respondents who experienced trial-related financial hardship most often reported expenses from travel (71%) and medical bills (58%)).

reported outcomes, or other study-related activities, and these related digital health technologies should be treated as participation-enabling support rather than an inducement. Providing supporting devices and technology, such as smartphones, tablets, wearable devices, or smartwatches, may also be useful when necessary to collect study data. Covering remote patient monitoring costs can be particularly helpful in supporting certain representative patient populations, for example patients in rural locales.

Investigational device exemption (IDE) control-arm trials also warrant support for participant cost-sharing because control-arm participants receive no therapeutic benefit from the study. Although recent OIG advisory opinions provide some clarity that such support is permissible, a specific safe harbor would still be beneficial.

Because clinical trial participants do not provide professional services, the strict fair market value (FMV) framework used in the AKS Personal Services Safe Harbor is not the most appropriate compensation metric. A more flexible, facts-and-circumstances-specific "reasonableness" standard tied to the nature, duration, and burden of the study, the difficulty of recruiting patients who meet inclusion criteria, and other relevant factors may be more workable. Any regulatory framework should also account for the reality that long-duration trials—some extending five to ten years or more—involve costs that increase over time.

Above all, sponsors and sites should have reasonable flexibility to design participant-support programs tailored to the unique needs of, and facts and circumstances surrounding, each trial, including the target patient population, the drug or device involved, and the trial site.

D. Value Caps and Other Remuneration Limitations

Please explain whether clinical trials currently impose value caps or other limits, like demonstrated financial need, or reimbursement only for actual documented costs incurred, for any remuneration given to clinical trial participants. Please explain whether any such value caps or limits permit remuneration adequate to facilitate participation in clinical trials. Describe what limitations, such as value caps, would guard against the harms resulting from fraud and abuse.

AdvaMed Response: Limitations on study participant remuneration, such as requirements to demonstrate financial need or document each actual cost incurred, can undermine efforts to reduce the practical burdens associated with clinical trial participation in two ways. First, such requirements may discourage potential study sites from participating in clinical trials because they are unwilling or unable to shoulder the administrative burden of managing those requirements, thereby reducing the number of sites available to enroll participants. Second, prospective participants may be deterred from enrolling because the prospect of paperwork requirements, on top of the typical burdens of study participation, may make reimbursement seem not worth the time and effort required. Instead, reimbursement and support should be based on the reasonable trial-related expenses and burdens associated with participation.

As noted above, a "reasonable" standard tailored to the facts and circumstances is preferable to a strict FMV requirement, given the difficulty of applying an FMV metric to costs such as travel time or childcare. A fixed value cap may not adequately account for changing costs, regional differences, or the increasing complexity and innovation associated with certain clinical trials. It could also unintentionally limit sponsors' ability to support participants in studies involving higher-cost or more complex investigational

devices or procedures. Any limitation should account for the reality that many long-duration trials involve costs that increase over time and should permit adjustments within a single trial to reflect those increases.

E. Role of IRBs

Please explain the role of an Institutional Review Board ("IRB") in reviewing the provision of remuneration to clinical trial participants and whether an IRB's review of the type, amount, and frequency of remuneration provided to clinical trial participants and the advertising of that remuneration is a meaningful safeguard against the harms resulting from fraud and abuse. If so, please specify the rationale and the standards the IRB should use.

AdvaMed Response: IRBs play a central and consistent role in reviewing clinical trial remuneration. As a general matter, the trial sponsor obtains overarching IRB approval for a trial, while individual trial sites typically submit separately to a designated central or local IRB. IRBs focus on participant health, safety, and well-being. As part of their review, IRBs assess whether proposed remuneration could exert coercion or undue influence on a participant's decision to enroll in, or remain in, a clinical trial. Consistent with longstanding ethical principles and applicable regulations, IRBs review the proposed method, amount, and timing, of remuneration, as well as descriptions of remuneration in informed consent materials and recruitment advertisements, to ensure the payments are presented appropriately and do not unduly influence participation decisions.[2] Through the informed consent process, participants are informed of the trial sponsor and receive a trial procedure-based breakdown of applicable remuneration; the IRB also reviews this information. OIG may therefore appropriately view IRB review and approval as an existing safeguard with respect to site and sponsor decisions regarding remuneration. However, IRBs are established to protect the rights, safety, and welfare of research participants, not to regulate financial arrangements or police fraud and abuse risks. While IRB review serves as a meaningful safeguard by providing independent oversight of participant remuneration and helping ensure that payments are not structured in a manner that could improperly influence participation decisions, expanding the role of the IRB to determine whether remuneration is appropriate from a fraud and abuse perspective would impose a substantial administrative burden and is not typically within the expertise of most IRBs.

F. Safeguards Against Patient Steering

Please enumerate any safeguards that should be in place to ensure clinical trial participants who receive remuneration to participate in a clinical trial are not inappropriately steered to items or services offered by the individual or entity offering the remuneration outside the clinical trial.

AdvaMed Response: Appropriate safeguards should ensure that remuneration facilitates participation in the clinical trial and does not influence participants' future health care decisions or utilization outside the research setting. These safeguards may include providing reasonable stipends or reimbursement based on reasonable estimates of expenses and burdens directly related to study participation and/or study-specific visits, such as mileage, food, and lodging costs; ensuring that participants are not required or

[2] FDA, "Payment and Reimbursement to Research Subjects: Guidance for Institutional Review Boards and Clinical Investigators" (Jan. 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects.

expected to continue using the sponsor's device, product, or services after the trial as a condition of receiving remuneration; ensuring that study subjects are not expected to continue using or obtaining unrelated services from the study site; permitting participants with an implanted investigational device, when appropriate under the study protocol, to elect device removal at the sponsor's expense at the conclusion of the study; and, in studies with control groups, allowing eligible participants to cross over to active treatment only as specified in the IRB-approved protocol, rather than as an incentive tied to remuneration. Assuring that these safeguards are clearly explained in the informed consent form will also help avoid influencing participants or steering them to other items or services offered by the sponsor or the study site.

Overall, tying remuneration to a reasonableness standard and burden-based factors, as discussed above, rather than to a participant's use of or referrals to a sponsor's products or services, can reduce incentives for, or the appearance of, steering. Moreover, IRB review of the method, amount, and timing of remuneration provides an existing layer of independent oversight.

As further discussed below, AdvaMed recommends that OIG adopt a new AKS safe harbor [and Beneficiary Inducements CMP exception] related to clinical trial remuneration. Any such framework should provide flexibility to support transportation assistance, digital health technologies, remote participation tools, and other participation-enabling support that reduce financial, geographic, and logistical barriers to enrollment and retention while maintaining appropriate safeguards. AdvaMed has proposed text, in Attachment A, that reflects these priorities.

G. Remuneration Across Product Development Stages

Please explain whether remuneration to clinical trial participants is provided during all stages of product development (e.g., phase 1–4 clinical trials) and whether different amounts or types of remuneration are necessary to promote participation in early-stage versus late-stage development. To the extent that there is more uncertainty regarding how the Federal anti-kickback statute and Beneficiary Inducements CMP would apply to certain stages of development, please explain. Describe what, if any, limitations would guard against the harms resulting from fraud and abuse in connection with different phases of clinical trials.

AdvaMed Response: Remuneration across all phases of research and product development can benefit clinical trial outcomes. The most effective types and amounts are based on the time, burden, inconvenience, and expenses associated with participation. Early feasibility studies, for example, may involve greater risk, more frequent study visits, and more diagnostic testing, which may justify higher remuneration than studies with less demanding protocols. In early feasibility and investigational device exemption (IDE) studies involving novel or innovative interventions, the cost of the procedure or intervention may not be covered by the subject's insurance. In such circumstances, it is beneficial for sponsors (including device manufacturers) to have the option of covering procedural costs through remuneration to participating hospitals as part of a contractual agreement. In some cases, a phase-based sliding scale may be appropriate because an early-phase participant may not receive a direct treatment benefit from the investigational product, while cost-sharing, copayment, or deductible support may still meaningfully facilitate enrollment.

However, remuneration assessments should not depend entirely on phase. Sponsors and regulators should instead ensure that remuneration is reasonable and proportionate to research-related time, inconvenience, travel, and study burdens.

H. Remuneration by Trial Type or Category

Please identify and explain if there are specific types or categories of clinical trials that should or should not pay remuneration to clinical trial participants due to that type's or category's relative risk of the harms resulting from fraud and abuse under the Federal anti-kickback statute and Beneficiary Inducements CMP. For example, please explain whether remuneration to clinical trial participants should only be protected under the Federal anti-kickback statute and Beneficiary Inducements CMP when provided to participants of government-sponsored clinical trials.

AdvaMed Response: Remuneration should be evaluated based on its purpose, the burden imposed on participants it is meant to address, and the safeguards in place, rather than the type of study alone. Post-market studies involving commercially available devices reimbursed by Federal health care programs may warrant additional guidance because they often involve larger patient populations, established investigators and research sites, and participants who already receive the device as part of routine clinical care. Even so, participants may incur additional research-related burdens, such as protocol-required follow-up visits, data collection, remote monitoring, or travel to specialized sites (including national travel in some rare disease trials) that support appropriate remuneration in this context. It would also be helpful to distinguish post-market studies required by FDA or conducted to generate additional safety, effectiveness, or real-world evidence from post-market activities designed primarily to support commercial promotion.

I. Advertising Limitations on Remuneration

Please explain whether there should be advertising limitations relating to remuneration to clinical trial participants to protect the integrity of the clinical trial and guard against the harms resulting from fraud and abuse.

AdvaMed Response: OIG guidance should clearly distinguish remuneration provided in connection with clinical research, including post-market clinical studies required by the FDA or conducted to generate additional safety and effectiveness data, from remuneration associated with the commercial promotion of marketed products or services. Communications regarding participant remuneration in studies should be permitted to the extent they accurately describe the availability, nature, and conditions of such remuneration and are intended to facilitate participation, rather than as marketing or promotion. Remuneration intended to reduce financial and logistical barriers to bona fide clinical research serves a fundamentally different purpose from remuneration offered in connection with routine clinical care. Clear guidance distinguishing legitimate clinical research, including post-market studies, from commercial activities would address fraud and abuse concerns more effectively than advertising restrictions.

J. Proposed Safe Harbor and Beneficiary Inducements CMP Exception

Please identify what, if any, additional or modified safe harbors to the Federal anti-kickback statute or

exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP may be necessary to protect remuneration to clinical trial participants and any arrangements necessary to offer and provide such remuneration. Please explain any key provisions that should be included in any additional or modified safe harbor or exception. Specifically, and to the extent that you did not do so in response to the questions above, please describe what conditions would be appropriate to include in a safe harbor or exception to protect against the harms resulting from fraud and abuse in the context of such arrangements, including what, if any, disclosures should be required by such safe harbors or exceptions.

AdvaMed Response: AdvaMed recommends that OIG adopt a new AKS safe harbor related to clinical trial remuneration. Such safe harbor should incorporate a "reasonable" remuneration standard tailored to the facts and circumstances of each clinical trial. The standard should recognize that trials vary in size, scope, target populations, and other factors that may affect the appropriate form and level of remuneration. The text of our proposed safe harbor is set forth in Attachment A to this letter.

As discussed above, protection should extend to reasonable, study-specific patient-support programs that encourage enrollment and retention. These programs may include reasonable reimbursement for travel, transportation, lodging, and meals; cost-sharing assistance for the intervention or procedure; compensation for participant time; childcare, elder care, and caregiver supports when necessary; and support for other study-specific burdens, such as internet connectivity, remote participation tools, digital health technologies, and other study-required devices or equipment.

A safe harbor need not expressly limit the source of clinical trial remuneration because existing protections address remuneration sources: the informed consent process typically identifies the sponsor, remuneration flows through designated, site-specific budgets or other study administration processes, and the applicable IRB reviews the remuneration arrangements. To the extent sponsors or sites rely on third-party vendors to distribute stipends or expense support, OIG guidance should clarify that appropriately structured vendor administration is permissible when it is used to facilitate study-related support and is not tied to referrals, product use, or utilization outside the clinical trial.

OIG should also consider modifying the current AKS personal services and management contracts and outcomes-based payment arrangements safe harbor at 42 C.F.R. § 1001.952(d) to address bona fide clinical trial activities, including compensation for patient identification, recruitment, referral, and other study-site administrative activities performed in accordance with an IRB-approved study protocol.

Because the Beneficiary Inducements CMP regulations already exclude remuneration protected under AKS safe harbors, adoption of a new AKS safe harbor may provide sufficient CMP protection without a separate CMP exception.[3] To the extent OIG still determines that additional CMP-specific protection or guidance is necessary, OIG should establish a specific exception under the Beneficiary Inducements CMP for remuneration provided to clinical trial participants. Any such exception should permit sponsors to provide reasonable study-related remuneration when provided pursuant to an IRB-approved protocol, including cost-sharing assistance, reimbursement support for study-related expenses, stipends reflecting the time and burden of participation, and study-required technology or equipment. Alternatively, OIG could

[3] 42 C.F.R. § 1003.110.

expressly exclude bona fide clinical trial remuneration from the nominal value limitations applicable to the Beneficiary Inducements CMP.

K. Inadequacy of Existing Safe Harbors and CMP Exceptions

Please explain, with specificity, why any existing safe harbors to the Federal anti-kickback statute or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP do not adequately protect the arrangements necessary to effectuate the provision of remuneration to clinical trial participants.

AdvaMed Response: No existing safe harbor expressly addresses clinical trial participant remuneration and as a result industry participants and others lack explicit protection to engage in proper and necessary activities with respect to clinical trials. OIG has addressed related questions almost exclusively through individual advisory opinions issued over the past two decades. Because those opinions bind only the requesting parties, they leave similarly situated sponsors and sites without the benefit of that guidance. OIG's existing sub-regulatory guidance on beneficiary inducements and the "nominal value" gifts standard is also roughly two decades old and has not kept pace with current costs for travel, technology, and related support.

The AKS personal services and management contracts and outcomes-based payment arrangements safe harbor, in particular, is not well suited to arrangements involving payments for bona fide patient identification, recruitment, or referral activities related to clinical trials. In many cases, it is difficult to establish fair market value for these activities without considering the expected number of participants enrolled, yet compensation methodologies tied to enrollment may raise concerns that remuneration varies with the volume or value of referrals. As a result, sponsors and research sites lack clear guidance regarding how to structure compliant arrangements that support legitimate clinical research while avoiding fraud and abuse concerns.

Similarly, the existing Beneficiary Inducements CMP exceptions do not adequately address remuneration intended solely to reduce financial and logistical barriers to clinical trial participation because those exceptions were developed primarily for commercially available health care items and services rather than IRB-approved clinical research. Additional clinical trial-specific protection or guidance would provide greater certainty while supporting appropriate participant enrollment and retention.

L. Broader Impacts or Implications of Clinical Trial Remuneration

Please discuss any potential broader impacts or implications—and in particular, as they relate to the criteria set forth in section 1128D(a)(2) of the Act (e.g., an increase or decrease in access to health care services, an increase or decrease in costs to Federal health care programs)—that may result from the provision of remuneration to clinical trial participants, additional or modified safe harbors to the Federal anti-kickback statute, or exceptions to the definition of "remuneration" under the Beneficiary Inducements CMP. For instance, if remuneration would result in higher participation rates of federal health care program enrollees in clinical trials, could that lead to improved health care for individuals in those programs?

AdvaMed Response: Appropriately tailored remuneration for clinical trial participants, particularly as permitted through the proposed safe harbor in Attachment A, would provide public health benefits while posing minimal risk of increasing costs to Federal health care programs. We expect the potential impact on Federal health care program expenditures to be limited because clinical trials involve a finite number of study sites and participants, and remuneration would be restricted to facilitating participation in protocol-defined research activities rather than encouraging the use of medically unnecessary items or services. Greater flexibility to reimburse study-related costs and reduce financial barriers could increase Medicare and Medicaid beneficiaries' access to clinical research, resulting in more representative study populations and more generalizable clinical evidence. Increased participation may also improve enrollment and retention, reduce delays in study completion, and shorten the time needed to generate evidence supporting regulatory decision-making and patient access to new technologies. Overall, these changes would strengthen the efficiency, quality, and competitiveness of the U.S. clinical research ecosystem.

M. Opportunities for OIG Guidance

Are there opportunities where OIG could clarify its position through guidance as opposed to regulation? For example, would a Special Advisory Bulletin, an FAQ response, or other guidance offer sufficient protection in some instances? If so, please elaborate.

AdvaMed Response: Sub-regulatory guidance would be a meaningful complement to new rulemaking, particularly because a flexible reasonableness standard will require practical examples of arrangements OIG views as low risk.

OIG should issue an FAQ or Special Advisory Bulletin confirming that sponsors may provide appropriate cost-sharing assistance and other study-related remuneration to clinical trial participants, subject to clearly defined safeguards. The guidance should describe acceptable guardrails, such as limiting remuneration to protocol-related costs and burdens, prohibiting remuneration intended to influence future use of commercially available products or services, recognizing the role of IRB oversight, and identifying examples of remuneration structures that OIG would consider reasonable and not indicative of fraud or abuse.

OIG could also issue a Special Advisory Bulletin or other guidance distinguishing legitimate clinical research arrangements from the suspect payment arrangements discussed in its 1994 Special Fraud Alert regarding payments for referrals. The guidance could clarify whether, and under what circumstances, a clinical trial sponsor may compensate physicians or other providers for bona fide patient identification and referral activities related to enrollment in qualifying human clinical trials. It could also identify low-risk recruitment and patient-awareness activities, distinguish them from higher-risk arrangements, describe payment methodologies or compensation structures that present a low risk of fraud and abuse, and, where applicable, explain how those arrangements may satisfy the Personal Services and Management Contracts Safe Harbor.

Additional guidance would be particularly valuable for post-market clinical studies, where FDA-approved products are evaluated in a research setting. Clarifying the distinction between legitimate clinical research

activities and commercial promotion would provide greater certainty for sponsors, investigators, and research sites while promoting patient access to clinical trials and maintaining appropriate fraud and abuse protections.

If OIG does not pursue a safe harbor, it would be beneficial for OIG to update its existing Special Fraud Alert and advisory guidance addressing beneficiary inducements, as well as its "nominal value" gifts interpretation, both of which we view as outdated relative to current costs for travel, technology, and related categories of support.

III. Conclusion

Thank you for considering these comments and proposals. We would appreciate the opportunity to meet with OIG to discuss how AdvaMed can support OIG's ongoing efforts to protect legitimate, good-faith arrangements involving clinical trial remuneration while preventing fraud, waste, and abuse, including the issues addressed in this response. Please contact me at (202) 783-8700 or cwhite@advamed.org with any questions.

Sincerely,

Christopher L. White
General Counsel & Chief Policy Officer
Advanced Medical Technology Association (AdvaMed)

ATTACHMENT A

I. New AKS Safe Harbor for Clinical Trial Remuneration

AdvaMed proposes that OIG adopt a safe harbor for clinical trial remuneration as follows:

(*) Clinical trial remuneration. As used in section 1128B of the Act, "remuneration" does not include any payment or exchange of anything of value provided to facilitate a participant's enrollment or retention in a clinical trial, regardless of whether the payment or exchange is provided by the trial sponsor, an investigator, a research site, or another person or entity, as long as all of the following standards are met—

(1) The clinical trial is conducted pursuant to a clinical trial protocol that has been approved by an institutional review board (IRB) in accordance with applicable Federal regulations for the protection of human subjects.

(2) The type, method, amount, and timing of the remuneration, including any mechanism for adjusting the remuneration over the course of the clinical trial, is described in the informed consent materials, including the relevant materials pertaining to remuneration reviewed by the IRB as part of the IRB's review and approval of the protocol. Where the informed consent materials disclose, and the IRB reviews, a pre-specified adjustment mechanism (such as a periodic cost-of-living adjustment or a tiered schedule tied to defined trial milestones, procedures or phases), subsequent adjustments to remuneration made in accordance with that mechanism satisfy this paragraph without requiring further amendment of the informed consent materials or additional IRB review specific to each adjustment.

(3) The remuneration consists of one or more of the following categories of reasonable, study-specific support:

(i) Reimbursement for reasonable travel, transportation, lodging, and meal expenses incurred in connection with participation in the clinical trial;

(ii) Assistance with cost-sharing obligations, including copayments, coinsurance, and deductibles, attributable to items or services furnished in connection with the clinical trial, or with the cost of the intervention or procedure itself for newer, innovative technologies where the aforementioned payment assistance mechanisms are not available;

(iii) Reasonable compensation for the time, effort, inconvenience, and burden associated with protocol-required activities, which may, but need not, take the form of a per-visit or per-study stipend;

(iv) Reimbursement for childcare or elder care expenses incurred to facilitate participation;

(v) Reimbursement for internet or wireless connectivity, or the provision of technology or equipment (such as a smartphone, tablet, wearable device, or smartwatch), reasonably necessary to support remote monitoring, telehealth visits, electronic collection of patient-reported outcomes, or other study-related activities; or

(vi) Any other remuneration that is substantially similar in nature and purpose to the categories of support described in paragraphs (*)(3)(i) through (v) of this section, intended to reduce financial or logistical barriers to enrollment or retention, or to compensate for the time, effort, or burden associated with participation, based on the specific facts and circumstances of the clinical trial, including the target patient population, the drug, biological product, or device under investigation, and the trial site, provided that such remuneration satisfies the other standards of this safe harbor.

(4) The type and amount of remuneration provided under paragraph (*)(3) of this section is reasonable in light of the nature, duration, and burden of the clinical trial and the difficulty of recruiting and retaining participants who satisfy the trial's inclusion criteria, taking into account relevant facts and circumstances, such as the phase of the trial, the target patient population, the drug, biological product, or device under investigation, and the trial site.

(5) The remuneration is not conditioned on the participant continuing to use, following completion of the clinical trial, any drug, biological product, device, or other item or service manufactured, distributed, or furnished by the person or entity providing the remuneration, and the participant is not required or expected, as a condition of receiving the remuneration, to continue any such use.

(6) The remuneration is not conditioned on the participant obtaining services unrelated to the clinical trial from the study site or continuing to use the study site following completion of the clinical trial, and the participant is not required or expected, as a condition of receiving the remuneration, to obtain any such services or to continue any such use.(7) If the clinical trial involves a control group, any opportunity for a participant to cross over to active treatment is made available only as specified in the IRB-approved protocol, and is not offered or used as an incentive tied to remuneration.